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Public Health, Workforce, Quality, and Other Provisions in the America's Healthy Future Act (S. 1796)

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Summary

Health care reform is at the top of the domestic policy agenda for the 111th Congress, driven by concerns about the growing ranks of the uninsured and the unsustainable growth in spending on health care and health insurance. But efforts to improve access to care and control rising health care costs also will require changes to the health care delivery system. Experts point to a growing body of evidence of the health care system's failure to consistently provide high-quality care to all Americans. Major challenges to the delivery of high-quality care include improving patient safety by eliminating medical errors, eradicating disparities in care, reducing the burden of chronic disease, and eliminating unnecessary and ineffective care that compromises quality, drives up costs, and neglects the needs of patients.

The health reform debate has generated a number of proposals to address these challenges and improve the delivery of health care services. They include initiatives to encourage individuals to adopt healthier lifestyles, and to change the way that physicians and other providers treat and manage disease. Delivery reform proposals focus on expanding the primary care workforce, encouraging the use of clinical preventive services, and strengthening the role of chronic care management. However, health care delivery reform cannot happen unless mechanisms are in place to drive change in the systems of care. Key drivers include performance measurement and the public dissemination of performance information, comparative effectiveness research, adoption of health information technology (HIT), and, most importantly, the alignment of payment incentives with high-quality care.

Congress took an important step toward reforming the health care delivery system when it enacted the American Recovery and Reinvestment Act (ARRA; P.L. 111-5) in February 2009. ARRA included $1.1 billion for comparative effectiveness research and established an interagency advisory panel to help coordinate and support the research. It also incorporated the Health Information Technology for Economic and Clinical Health (HITECH) Act, which is intended to promote the widespread adoption of HIT for the electronic sharing of clinical data among hospitals, physicians, and other health care stakeholders.

Both the House and the Senate are now considering health reform legislation. On October 19, 2009, Senator Max Baucus introduced a comprehensive health care reform bill entitled the America's Healthy Future Act of 2009 (S. 1796, S.Rept. 111-89). The legislation is based on the Chairman's Mark that was ordered reported, as amended, by the Senate Finance Committee on October 13, 2009. This report summarizes the workforce, quality, prevention, and other selected provisions, including those related to elder justice, maternal and child health, and health care for veterans, in S. 1796. The Senate Health, Education, Labor, and Pensions (HELP) Committee approved the Affordable Health Choices Act (S. 1679), which addresses health care delivery reform issues such as expanding private health insurance coverage and expanding the health care workforce (see CRS Report R40831, *Public Health, Workforce, Quality, and Other Provisions in the Affordable Health Choices Act [S. 1679]*). H.R. 3962, the Affordable Health Care for America Act, was introduced in the House of Representatives on October 29, 2009. H.R. 3962 is based on H.R. 3200, America's Affordable Health Choices Act of 2009, which was originally introduced on July 14, 2009, and was reported separately on October 14, 2009, by three House committees: Education and Labor, Energy and Commerce, and Ways and Means.

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Introduction

Health care reform is at the top of the domestic policy agenda for the 111th Congress, driven by concerns about the growing ranks of the uninsured and the unsustainable growth in spending on health care and health insurance. Improving access to care and controlling rising costs will require changes to both the financing and delivery of health care. Experts point to a growing body of evidence of the health care system's failure to consistently provide high-quality care to all Americans.

In a November 2008 report outlining its goals for health reform, the National Priorities Partnership, representing all the major stakeholder groups in the health sector, identified four major challenges to the delivery of high-quality care.[1] The first is to improve patient safety by eliminating medical errors and other adverse events. These errors mostly result from faulty systems, processes, and conditions that lead to mistakes. The second challenge is to eradicate disparities in care. Racial and ethnic minorities and low-income groups face disproportionately higher rates of disease, disability, and mortality, largely because of variations in access to care, and quality of care. The third challenge is to reduce the burden of chronic disease, which affects almost half of all Americans and accounts for three-quarters of health care spending. The final challenge is to eliminate unnecessary and ineffective care that compromises quality, drives up costs, and neglects the needs of patients. According to the Institute of Medicine (IOM), an estimated 30%-40% of health care spending is wasted on unnecessary and even unsafe care.[2]

Health Care Delivery Reform

While primarily focused on health care financing issues, the health reform debate has generated a number of proposals to address these challenges and improve the delivery of health care services. They include initiatives to encourage individuals to adopt healthier lifestyles, and to change the way that physicians and other providers treat and manage disease. Delivery reform proposals focus on (1) expanding the primary care workforce, (2) encouraging the use of clinical preventive services, and (3) strengthening the role of chronic care management. The current system places a high value on specialty care, rather than primary care. Patients with multiple chronic conditions often receive care from several providers in different settings. Among other things, this can compromise patients' understanding of their conditions and ways to manage them. And the incomplete or inaccurate transfer of information among providers can lead to poor outcomes. Care coordination is seen as an important aspect of health care that helps avoid waste, and the over- and underuse of medications, diagnostic tests, and therapies.

Health workforce policy has emerged as an important component of the health reform debate. Transforming the nation's health care delivery system—from one that is focused on fragmented specialty care for acute illness to one that places a greater emphasis on primary care, disease prevention, and the coordination and management of care for chronic illness across settings—will require significant changes in health professions education and training. While some advisory groups have warned of a future physician shortage, based on the growing patient demand for services, others caution that simply adding more physicians to the current health care system will

[1] National Priorities Partnership, *National Priorities and Goals: Aligning Our Efforts to Transform America's Healthcare*. Washington, DC: National Quality Forum, 2008. For more information on the work of the Partnership, go to http://www.nationalprioritiespartnership.org/.

[2] Institute of Medicine, National Academy of Engineering, *Building a Better Delivery System: A New Engineering/Health Care Partnership*. Washington, DC: National Academies Press, 2005.

increase costs and not improve accessibility or quality. Currently, the number of physicians per capita varies significantly across the country. But that variation is largely driven by where physicians like to live and practice, rather than by patient need. Moreover, higher physician supply is not necessarily associated with better patient outcomes or satisfaction, or improved quality of care.[3] Instead of focusing on overall physician supply, health policy analysts recommend a workforce policy that couples the training of more primary care physicians (and other primary care providers) with the promotion and development of integrated systems of care.

Expanding the use of clinical preventive services is a key goal of delivery reform and often touted as having the potential to reduce health care costs. Such services include immunizations and other interventions that prevent the onset of disease (known as primary prevention), and screening tests that detect the presence of an incipient disease (known as secondary prevention). While there is clear evidence that clinical preventive services can improve health and may be cost-effective (i.e., providing good value for their cost), few of these interventions are projected to be cost-saving.[4]

Proponents of delivery reform have also embraced the concept of a medical home, intended to improve the quality of care through partnerships between patients and specially trained primary care physicians. The physician helps the patient manage his or her own care and coordinates services across settings (specialists' offices, hospitals, and laboratories) and types of care (acute, chronic, and preventive). Concern about the rising costs of treating chronic disease and the lack of coordination of care also has generated keen interest in disease management programs. These programs, typically focused on a specific disease such as diabetes, help patients manage their own care. Program elements include patient education, symptom monitoring, and adherence to treatment plans. Disease management programs share similarities with the medical home concept. But whereas the medical home is built around a physician-patient partnership, disease management programs typically are run by health plans or specialized vendors.

Drivers of Reform

Health care delivery reform cannot happen unless mechanisms are in place to drive change in the systems of care. Key drivers include performance measurement and the public dissemination of performance information, comparative effectiveness research, adoption of HIT, and, perhaps most importantly, alignment of payment incentives with high-quality care. Most health policy experts concede that improvements in the quality of health care will not be fully realized unless providers have financial incentives to modify the way they deliver health care services. Under fee-for-service, the predominant method of payment, physicians are paid based on the volume of billable services, rather than the value or quality of care they provide. Increasingly, public and private payers are linking a portion of provider payments to their performance on a set of quality measures. Policymakers are interested in expanding these pay-for-performance initiatives to incentivize other changes to the health care delivery system.

The use of performance measures to track the quality of care is growing in both the private and public health sectors, though concerns about the development and use of such data remain. The public reporting of quality information is seen as a necessary step in helping patients make informed choices about health care services and the organizations that provide them.

[3] David C. Goodman and Elliott S. Fisher, "Physician Workforce Crisis? Wrong Diagnosis, Wrong Prescription," *New England Journal of Medicine,* vol. 358, no. 16 (April 17, 2008), pp. 1658-1661.

[4] Joshua T. Cohen et al., "Does Preventive Care Save Money? Health Economics and the Presidential Candidates," *New England Journal of Medicine,* vol. 358, no. 7 (February 14, 2008), pp. 661-663.

American Recovery and Reinvestment Act

Congress took one step toward reforming the health care delivery system when it enacted the American Recovery and Reinvestment Act (ARRA; P.L. 111-5) in February 2009. ARRA included $17 billion in supplemental funding for biomedical research, public health, and other health-related programs within the Department of Health and Human Services (HHS), including $1.1 billion for comparative effectiveness research. It also established an interagency advisory panel to help coordinate and support the research. In addition, ARRA incorporated the HITECH Act, which is intended to promote the widespread adoption of HIT for the electronic sharing of clinical data among hospitals, physicians, and other health care stakeholders. Included in the ARRA health funding was $2 billion to fund HIT grant programs authorized by the HITECH Act.[5]

HIT, which generally refers to the use of computer applications in medical practice, is widely viewed as a necessary and vital component of health care reform. It encompasses interoperable electronic health records (EHRs)—including computerized systems to order tests and medications, and support systems to aid clinical decision making—and the development of a national health information network to permit the secure exchange of electronic health information among providers. The promise of HIT comes not from automating existing practices, but rather its use as a tool to help overhaul the delivery of care. HIT has the potential to enable providers to render care more efficiently; for example, by eliminating the use of paper-based records and reducing the duplication of diagnostic tests. It can also improve the quality of care by identifying harmful drug interactions and helping physicians manage patients with multiple conditions. Moreover, the widespread use of HIT could provide large amounts of clinical data for comparative effectiveness research, performance measurement, and other activities aimed at improving health care quality.

Overview of Report

On October 19, 2009, Senator Max Baucus introduced a comprehensive health care reform bill entitled the America's Healthy Future Act of 2009 (S. 1796, S.Rept. 111-89). The legislation is based on the Chairman's Mark which was ordered reported, as amended, by the Senate Finance Committee on October 13, 2009. S. 1796 consists of six titles. Title I addresses private health insurance, and would establish both a health insurance exchange and an individual mandate. Title II includes provisions related to prevention and wellness, and generally promotes preventive services. Title III addresses the quality and efficiency of health care, and would strengthen quality measurement. Title IV would promote transparency and integrity in the Medicare program. Title V includes a series of provisions intended to prevent health care fraud and abuse. Finally, Title VI contains revenue raising provisions.

This report summarizes the workforce, quality, prevention, and other provisions in Titles I, II, III, IV, and VI of S. 1796. The report groups the bill's provisions under the following headings: (1) health workforce; (2) health care quality; (3) health information technology; (4) prevention and wellness; (5) maternal and child health services; (6) health disparities; (7) emergency care; (8) health care for veterans; (9) elder justice; and (10) miscellaneous. In most instances, each section begins with some background on current law and practice so as to provide context for the subsequent brief descriptions of the bill's provisions. Unless otherwise stated, references to "the

[5] See P.L. 111-5; for more information, see CRS Report R40181, *Selected Health Funding in the American Recovery and Reinvestment Act of 2009*, coordinated by C. Stephen Redhead, and CRS Report R40161, *The Health Information Technology for Economic and Clinical Health (HITECH) Act*, by C. Stephen Redhead.

Secretary" refer to the Secretary of HHS. A list of all the acronyms used in the report can be found in **Appendix**.

A companion report, CRS Report R40831, *Public Health, Workforce, Quality, and Other Provisions in the Affordable Health Choices Act (S. 1679)*, summarizes comparable provisions in the Senate HELP Committee's health reform legislation, the Affordable Health Choices Act (S. 1679).[6]

Health Workforce

Medicare Graduate Medical Education Payments

Medicare pays the costs of graduate medical education (GME) by making two types of payments to teaching hospitals. First, direct graduate medical education (DGME) payments help cover the costs of the residency training program, including resident salaries and benefits, supervisory physician salaries, and administrative overhead expenses. DGME payments are calculated based on the product of three factors: a hospital-specific per resident amount, a weighted count of full-time equivalent (FTE) residents supported by the hospital, and the hospital's Medicare patient share. Second, indirect medical education (IME) payments, which vary with the intensity of a hospital's residency program, are intended to compensate hospitals for the higher costs of patient care in teaching hospitals. Those costs are the result of such factors as having sicker patients and the fact that inexperienced residents may order more tests. The IME adjustment is a percentage add-on to a hospital's Medicare payments for inpatient care and is based, in part, on the hospital's resident-to-bed ratio. Medicare includes the time that residents spend in both patient care and non-patient care activities, including didactic activities, when calculating DGME payments. When calculating IME payments, however, only the time spent in patient care activities is included. In 2008, Medicare DGME and IME payments totaling an estimated $9 billion were paid to more than 1,100 teaching hospitals to educate and train about 90,000 residents, equivalent to approximately $100,000 per resident. Health policy analysts view Medicare GME payments as a potentially important instrument for shaping future health workforce policy; for example, by linking the subsidies to delivery system reform and by structuring them to encourage the training of more generalists and to increase the amount of time residents spend in non-hospital settings such as community health centers (CHCs) and rural health clinics.[7]

With certain exceptions, Medicare caps the number of residents used to calculate GME payments for individual teaching hospitals at the level reported at the end of 1996. The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 permitted a one-time redistribution of up to 75% of a teaching hospital's unused resident positions to hospitals seeking to increase their medical residency programs, according to specific priorities. Medicare does not set targets for the type or mix of resident physicians that a hospital trains, nor are Medicare GME payments linked to promoting or fostering specific goals in medical education.

Medicare allows teaching hospitals to receive DGME and IME payments for the time residents rotate in non-hospital settings provided (1) they are performing patient care, and (2) the hospital pays all or substantially all (i.e., 90%) of the costs of the training at the non-hospital site, which

[6] CRS Report R40831, *Public Health, Workforce, Quality, and Other Provisions in the Affordable Health Choices Act (S. 1679)*, coordinated by Kirsten J. Colello and C. Stephen Redhead.

[7] For a recent review of medical education in the United States and an analysis of the GME program and its potential role in health care delivery reform, see the Medicare Payment Advisory Commission's June 2009 *Report to Congress: Improving Incentives in the Medicare Program*, Chapter 1, at http://www.medpac.gov/chapters/Jun09_Ch01.pdf.

include the resident stipends and fringe benefits and the costs associated with supervising physicians. Time spent in non-patient care activities in the non-hospital setting is not counted when calculating either type of payment. A hospital that jointly operates a residency program with another hospital cannot include the time spent by residents working at a non-hospital site if it incurs all or substantially all of the costs for only a portion of the residents in that program at the non-hospital site. Additional regulatory requirements discourage rotations in non-hospital settings. Moreover, hospitals have a financial incentive to retain the often lower-cost clinical labor that residents provide. While experts see value in having residents gain experience in non-hospital settings such as CHCs and nursing facilities (NFs), residency programs today are largely based in inpatient, acute-care teaching hospitals. S. 1796 includes the following four sections which would make changes to Medicare to address these and related issues.

Sec. 3032. Distribution of Additional Residency Positions

This section would establish criteria to be used to reduce the otherwise applicable resident limit for hospitals with unused residency positions, as defined, and direct the Secretary to redistribute those unused positions and assign them to other qualifying facilities. Rural hospitals with fewer than 250 beds would be exempt from the redistribution of any of their unfilled positions.

A hospital that qualifies for an increase in residency positions would have to maintain its base level of primary care residents and ensure that not less that 75% of the additional positions are in primary care or general surgery residency. When determining the increase in a hospital's resident limit, the Secretary would take into account such factors as the likely speed with which the hospital would fill the positions, and whether the hospital would take part in an innovate delivery model that promotes quality and care coordination. Residency positions would be allocated, according to a specified formula, among the following qualifying facilities: (1) hospitals located in states with low resident-to-population ratios; (2) hospitals located in states with a high percentage of the population living in a health professional shortage area (HPSA); and (3) rural hospitals.

The section also would establish the criteria used to calculate DGME and IME payments for hospitals that receive redistributed residency positions.

Sec. 3033. Counting Resident Time in Outpatient Settings and Allowing Flexibility for Jointly Operated Residency Training Programs

This section would require that all time spent by a resident be counted towards the DGME payment, regardless of the setting, provided the hospital continues, or in the case of a jointly operated residency program, the involved entities continue to incur the costs of the stipends and the fringe benefits of the resident during the time spent in that setting. Further, all the time spent by a resident in patient care activities in a non-hospital setting would be counted towards the IME payment, provided the hospital continues, or in the case of a jointly operated residency program, the involved entities continue to incur those same costs.

Sec. 3034. Rules for Counting Resident Time for Didactic and Scholarly Activities and Other Activities

This section would require that resident time spent in certain non-patient care activities—including attending conferences and seminars, but not research unless it is associated with the treatment or diagnosis of a patient—in a non-hospital setting primarily engaged in furnishing patient care be counted towards the DGME payment. In addition, Medicare would count all the

vacation, sick leave, and other approved leave spent by the resident as long as the leave time does not extend the training program's duration.

When calculating IME payments, Medicare would adopt the same rules for counting residents' leave time. Resident time spent in hospital settings (as defined) on certain non-patient care activities—including attending conferences and seminars, but not research unless it is associated with the treatment or diagnosis of a patient—would count towards the IME payment.

Sec. 3035. Preservation of Resident Cap Positions from Closed and Acquired Hospitals

This section would direct the Secretary, by rulemaking, to establish a process to redistribute medical residency slots from a hospital with an approved residency program that closes on or after August 1997 to increase the otherwise applicable residency limit for other hospitals. The residency positions would be redistributed based on a specified priority order, with first priority given to hospitals located in the same or contiguous core-based statistical area as the hospital that closed. A special rule would be established for certain hospitals acquired with approval of a bankruptcy court.

Other Workforce Provisions

S. 1796 contains several other health workforce provisions that would: (1) address a national workforce strategy; (2) fund demonstration projects to address health professions workforce needs and extend funding to family-to-family health information centers; (3) fund teaching health centers to establish or expand primary care residency programs; (4) allow time spent teaching to count as service under the National Health Service Corps (NHSC) program; (5) make Medicare payments to teaching health centers for direct graduate medical education costs and other indirect costs associated with residency training programs that increase training and improve access to primary care services; and (6) establish a graduate nurse education demonstration program in Medicare. The following provides further detail on these provisions.

Sec. 3036. Workforce Advisory Committee

This section would require the Secretary to establish a Workforce Advisory Committee comprised of members appointed by the Secretary among specified groups, including public health experts, health insurers, and external stakeholders and representatives of health care professionals. The Committee would be required to develop and submit to Congress and relevant federal agencies a national workforce strategy to recruit, train, and retain a health care workforce that meets the current and projected health care needs of the United States. The Committee would be required to consult with relevant federal agencies and with state and local entities in developing such national workforce strategy. The Committee would also be required to conduct (1) a study on the U.S. health care workforce and (2) studies on specific high-priority topics, as described, and submit reports to Congress and relevant federal agencies with recommendations for legislation and administrative action, as determined appropriate. These reports would also be made publicly available.

Sec. 3037. Demonstration Projects to Address Health Professions Workforce Needs; Extension of Family-to-Family Health Information Centers

This section would amend Title XI of the Social Security Act (SSA) by adding the following new **Sec. 1130B** "Demonstration Projects to Address Health Professions Workforce Needs"

establishing two separate demonstration projects. The first would require the Secretary of HHS, in consultation with the Secretary of Labor, to award grants to conduct demonstration projects that would provide individuals receiving assistance under the State Temporary Assistance for Needy Families program (TANF) and other low-income individuals with the opportunity to obtain education and training for occupations in the health care field that pay well and are expected to either experience labor shortages or be in high demand. The second would require the Secretary to award grants to states to conduct demonstration projects for the purposes of developing core training competencies and certification programs for personal or home care aides. It would require $85 million to be appropriated to the Secretary of HHS, out of any funds in the Treasury not otherwise appropriated, to carry out both demonstration projects for each of FYs 2010 through 2014. The Secretary would be required to use $5 million of the amount appropriated for each of FYs 2010 through 2012 to carry out the second demonstration project. After FY2012, no appropriated funds would be required to carry out this project.

The section would also amend **SSA Sec. 501(c)(1)(A)(iii)**, which authorizes sums to be appropriated for the purpose of enabling the Secretary (through grants, contracts, or otherwise) to provide for special projects of regional and national significance for the development and support of family-to-family health information centers. Specifically, it would strike reference to FY2009 and insert new language that would appropriate to the Secretary, out of any money in the Treasury not otherwise appropriated, $5 million for each of FYs 2009 through 2012 to provide for the development and support of these centers.

Sec. 3038. Increasing Teaching Capacity

This section would amend Title VII, Part C of the PHSA to insert a new **Sec. 749** "Teaching Health Centers Development Grants" authorizing the Secretary to award grants to teaching health centers to establish newly accredited or expanded primary care residency programs. It would require that grants be awarded for not more than two years with the maximum award of $500,000. The Secretary would be required to give priority to funding training programs at federally Qualified Health Centers (FQHCs), Rural Health Centers (RHCs), Indian health centers, and to newly established residency programs, integrated rural training programs, rural training tracks, and to residencies with a mission to train physicians for rural and underserved practice. The Secretary would be required to give further preference to applications that document an existing affiliation agreement with an Area Health Education Center (AHEC). It would authorize to be appropriated $25 million for FY2010, $50 million for FY2011 and FY2012, and such sums as may be necessary (SSAN) for each fiscal year thereafter. No more than $5 million annually may be used for technical assistance program grants.

The section would amend **PHSA Sec. 338C(a)** to allow up to 50% of the time spent teaching to count as full-time service for the purpose of an individual fulfilling the contractual NHSC service obligation for scholarship or loan repayment. This provision would not necessarily apply to individuals who are fulfilling their NHSC service requirement through work in private practice.

It would also amend Medicare statute to insert a new **SSA Sec. 1866F** requiring the Secretary, for purposes of increasing training and improving access to primary care services, to make payments to qualified teaching health centers for direct graduate medical education costs and other indirect costs associated with operating approved graduate medical residency training programs. The Secretary would determine the basis of payment and funding calculations for both the direct and indirect payments and would promulgate regulations under existing rulemaking requirements to establish this program. These payments would be in addition to any indirect or direct graduate medical education payments made to teaching hospitals and would not count against the limitation on the number of total full time equivalent residents paid for by Medicare in teaching

hospitals. A total of $230 million would be transferred from the Medicare Part A Hospital Insurance Trust Fund for the period of fiscal years 2011 to 2015 with amounts transferred remaining available until expended.

Sec. 3039. Graduate Nurse Education Demonstration Program

This section would require the Secretary to establish a graduate nurse education demonstration program in Medicare. Under the demonstration program, eligible hospitals would receive Medicare reimbursement for educational costs, clinical instruction costs, and other direct and indirect costs attributed to providing advanced practice nurses with qualified training. An advanced practice nurse would include a clinical nurse specialist, nurse practitioner, certified registered nurse anesthetist, and certified nurse midwife as defined by Medicare statute. Advance practice nurses would receive training in skills necessary to provide primary care, preventative care, transitional care, chronic care management, and other nursing services appropriate for the Medicare-eligible population. At least half of all clinical training would occur in non-hospital community-based care settings. However, the Secretary would be authorized to waive this requirement for eligible hospitals located in rural and medically underserved areas. For any year, Medicare's payment amount would not exceed the amount of training costs attributed to an increase in the number of advance practice nurses enrolled in a qualified program during the year compared to the average number who graduated from that program in each year from January 1, 2006 to December 31, 2010 (as determined by the Secretary). To carry out this section, there would be appropriated, out of any funds in the Treasury not otherwise appropriated, $50 million dollars for each of fiscal years 2012 through 2015 with amounts remaining available until expended.

Quality

Background and Issues

Numerous stakeholders, including policymakers, have engaged in a wide range of efforts to try to address the issue of health care quality. These efforts have generally focused on improving and refining metrics for measuring the quality of care delivered in a number of settings; publicly reporting comparative information on quality performance; and, in some cases, using metrics as the basis for payment policies to demand provider accountability (value-based purchasing). However, these efforts have not generally been guided by a single federal strategy, entity, or set of priorities or goals, nor have they benefitted from a coordinated infrastructure specifically devoted to improving health care quality. The following describes provisions in S. 1796 that would address the issues of quality measurement; comparative effectiveness research; and Medicare and Medicaid nursing homes and other long term care (LTC) facilities.

Quality Measurement

There are no provisions in current law that require the development of national priorities for performance improvement (directed either at the Secretary or the Agency for Healthcare Research and Quality (AHRQ)). However, the Secretary is required by law to have in effect a contract with a consensus-based entity to perform a number of duties, including to synthesize evidence and convene stakeholders to make recommendations on an integrated national strategy and priorities for health care performance measurement in all applicable settings.

AHRQ has significant existing statutory authorities under PHSA Title IX with respect to the development of quality measures. This includes promoting health care quality improvement by conducting and supporting research that develops and presents scientific evidence regarding all aspects of health care, including methods for measuring quality and strategies for improving quality. In addition, AHRQ's role includes the ongoing development, testing, and dissemination of quality measures, including measures of health and functional outcomes, and the compilation and dissemination of health care quality measures developed in the private and public sector.

Current law does not set forth a process for, or require, multi-stakeholder input into the selection of quality measures by the Secretary for use in Centers for Medicare and Medicaid Service (CMS) quality programs, such as Medicare's Physician Quality Reporting Initiative (PQRI) or the Reporting Hospital Quality Data for Annual Payment Update (RHQDAPU) program.

S. 1796 includes the following four sections addressing quality measurement, which would require the development of an explicit national strategy for quality improvement; establish an interagency working group to advance quality efforts at the national level; develop a comprehensive repertoire of quality measures; and formalize quality measure endorsement and implementation.

Sec. 3011. National Strategy

This section would amend Title XVIII of the SSA to insert a new **Sec. 1890A,** "National Strategy for Quality Improvement in Health Care," which would direct the Secretary to establish a national quality improvement strategy, to include both the development of national priorities for improvement and a comprehensive strategic plan to achieve these priorities. The Secretary would be required to ensure that the national priorities for improvement would achieve certain aims (e.g., reducing health disparities, improving federal payment policy to emphasize quality and efficiency). In addition, in identifying these priorities, the Secretary would be required to consider both the recommendations submitted by qualified consensus-based entities and the recommendations of the Interagency Coordinating Working Group on Health Care Quality, established under Section 3012 of this Act.

The national strategy would also include a comprehensive strategic plan to achieve the national priorities. At a minimum, the strategic plan would include provisions for addressing coordination among agencies within HHS; agency-specific strategic plans and annual benchmarks to achieve the priorities; a process for regular reporting by the agencies to the Secretary on the implementation of the strategic plan; strategies to align incentives among public and private payers with regard to quality and patient safety efforts; and incorporation of quality improvement and measurement in the strategic plan for HIT (required by ARRA).

The Secretary would update the national strategy not less than triennially and the first report would be due to Congress not later than December 31, 2010. Any update would include a review of short and long term goals as well as an analysis of progress in meeting these goals. In addition, the Secretary would create an Internet website to make public information regarding the national priorities for health care quality improvement; the agency-specific strategic plans for health care quality; and other information the Secretary may determine to be appropriate.

Sec. 3012. Interagency Working Group on Health Care Quality

This section would require the President to convene a working group consisting of senior level representatives of relevant federal departments and agencies[8] with the goals of achieving collaboration, cooperation and consultation between federal departments and agencies with respect to developing and disseminating strategies, goals, models, and timetables that are consistent with the national priorities for improvement and avoiding duplication of quality improvement efforts and resources. The Working Group would be chaired by the Secretary, and members of the Working Group would serve as Vice Chair on a rotating basis. Not later than a date determined appropriate by the Secretary, and annually thereafter, the Working Group would submit a report to the relevant Committees of Congress, and make publicly available, a report on the progress and recommendations of the Working Group.

Sec. 3013. Quality Measure Development

This section would amend Title XVIII of the SSA to insert a new **Sec. 1890B**, "Quality Measure Development," which would facilitate quality measure development by requiring the Secretary to identify measure gaps and award grants to entities to develop measures in these gap areas. This section would require the Secretary to identify gaps where no quality measures exist, or where existing quality measures need improvement, updating or expansion consistent with the national strategy and priorities. The Secretary would award grants, contracts or intergovernmental agreements to eligible entities for purposes of developing, updating, or expanding quality measures in identified gap areas. In awarding these grants, contracts or agreements, the Secretary would give priority to the development of measures that allowed the assessment of certain characteristics, including, for example, the assessment of health outcomes and functional status of patients and patient experience and satisfaction. Entities eligible for a grant or contract under this section would have to meet certain criteria, including having demonstrated expertise and capacity in the development and evaluation of quality measures and having procedures in place to take into account the view of payers or providers whose performance will be assessed by the measures and the views of other parties who will use the measures. Measures developed by entities receiving such grants, contracts or agreements would have to meet certain requirements (e.g., be free of charge to users, be publicly available). The Secretary would be allowed to use amounts available under this section to update and test quality measures endorsed by a qualified consensus-based entity or adopted by the Secretary. The section would authorize to be appropriated $75 million for each of the fiscal years 2010 through 2014 to carry out this section.

Sec. 3014. Quality Measure Endorsement

This section would amend Title XVIII of the SSA to insert a new **Sec. 1890C,** "Quality Measure Endorsement," which would allow for the provision of a grant or contract to a qualified consensus-based entity to carry out a number of duties, including identifying gaps in endorsed quality measures, updating endorsed measures, and making recommendations to the Secretary for national priorities for performance improvement. This entity would provide a report to the

[8] Relevant federal departments and agencies shall include The Centers for Medicare and Medicaid Services (CMS), National Institutes of Health (NIH), Centers for Disease Control and Prevention (CDC); Food and Drug Administration (FDA), The Health Resources and Services Administration (HRSA), The Agency for Healthcare Research and Quality (AHRQ), and the Administration on Children and Families within The Department of Health and Human Services (HHS); The Department of Labor; The Department of Defense; The Department of Veterans Affairs; The Veterans Health Administration; The Department of Commerce; The Office of Personnel Management; The Office of Management and Budget; The U.S. Coast Guard; The Federal Bureau of Prisons; The National Highway Transportation and Safety Administration; and The Federal Trade Commission.

Secretary outlining where gaps exist, and regarding areas in which evidence is insufficient to support endorsement of quality measures in priority areas identified by the Secretary under section 3011. This entity would also evaluate evidence and convene multi-stakeholder groups to make recommendations to the Secretary for national priorities for improvement. In addition, this entity would provide guidance on the selection of measures for use in public reporting or federal health programs. These measures would be selected from those endorsed by the entity and those that have not been considered for endorsement by the entity, but are used, or proposed to be used, by the Secretary in federal health programs.

This section would require the Secretary to establish a pre-rulemaking process to obtain input on the selection of measures. Under this process, the Secretary would be required to make public a list of measures being considered for selection with respect to quality reporting and payment systems under Title XVIII of the SSA. Not later than February 1st of each year, beginning with 2011, the entity would be required to transmit to the Secretary the guidance of the multi-stakeholder groups.

With respect to endorsed quality measures, the Secretary could make a determination to use such measures only after taking into account the guidance of the multi-stakeholder groups as provided through the pre-rulemaking process. With respect to non-endorsed measures, the Secretary could use a measure that has not been endorsed, provided that the Secretary transmits the measure to the entity for consideration for endorsement and for the multi-stakeholder consultation process; publishes the rationale for the use of the measure in the *Federal Register*; and phases out use of the measures upon a decision of the entity not to endorse the measure, contingent on the availability of an adequate alternative endorsed measure.

Not less than once every three years, the Secretary would be required to review quality measures used by the Secretary to determine whether to maintain use of such measures or to phase them out. The Secretary would also set forth a process to disseminate measures used by the Secretary and incorporate such measures, where applicable, in workforce programs, training curricula, payment programs, and any other means of dissemination deemed appropriate by the Secretary. The Secretary would establish a process to disseminate such quality measures to the Working Group established in Section 3012 of this Act. The Secretary would be allowed to contract with one or more entities to carry out this dissemination process. In addition, the Secretary would be required to provide technical assistance to providers of services and suppliers required to report on measures under Title XVIII of the SSA. For purposes of carrying out this section, the Secretary would provide for the transfer of $50 million for each of the fiscal years 2010 through 2014 from the Federal Hospital Insurance Trust Fund and the Federal Supplementary Medical Insurance Trust Fund to the CMS Program Management Account.

Comparative Effectiveness Research

ARRA provided $1.1 billion for comparative effectiveness research and created the Federal Coordinating Council for Comparative Effectiveness Research (FCCCER), an interagency advisory group that is required to report to the President and Congress annually.[9] S. 1796 has two provisions that would establish a new private, non-profit corporation to be called the Patient-Centered Outcomes Research Institute, and which would extend the responsibilities of FCCCER with respect to this new Institute.

[9] On June 30, 2009 FCCCER released its annual "Report to the President and the Congress." The report can be found at http://www.hhs.gov/recovery/programs/cer/cerannualrpt.pdf.

Sec. 3501. Comparative Effectiveness Research

This section would authorize the establishment of a private, nonprofit corporation called the Patient-Centered Outcomes Research Institute. The Institute would assist patients, clinicians, purchasers, and policy makers in making informed health decisions by advancing the quality and relevance of clinical evidence through research and evidence synthesis. The Institute's 15-member Board would be appointed by the U.S. Comptroller General and would include members representing a broad range of groups, including patients and health care consumers, physicians and surgeons, private payers, and pharmaceutical, device, and diagnostic manufacturers, and others.

The Institute could enter into contracts with federal agencies as well as with appropriate private sector research or study-conducting entities for the management and conduct of research. The Institute would, as appropriate, appoint expert advisory panels to assist in identifying research priorities and establishing the research project agenda.

The Institute would establish a methodology committee, consisting of no more than 17 members appointed by the Comptroller General, which would have responsibility for developing and improving the science and methods of comparative effectiveness research. The methodology committee would establish and maintain standards regarding clinical outcomes measures, risk-adjustment, and other aspects of research and assessment. The methodology committee would also be required to contract with the IOM to examine (1) methods by which aspects of health care delivery systems, such as benefit design, could be assessed and compared for effectiveness, risks, benefits, advantages, and disadvantages in a scientifically valid and standardized way; and (2) methods by which efficiency and value could be assessed in a scientifically valid and standardized way.

The Institute would disseminate the findings of research to clinicians, patients, and the public in a comprehensible manner and form so that they are useful to patients and providers in making health care decisions. The Institute would be prohibited from disseminating research findings that would include practice guidelines, coverage recommendations, or policy recommendations. The Institute would not mandate coverage, reimbursement, or other policies for any public or private payer, and none of the reports or research findings would be construed as mandates, guidelines, or policy recommendations. The Secretary would be prohibited from denying coverage based solely on a study conducted by the Institute.

A new Patient-Centered Outcomes Research Trust Fund would be created in the U.S. Treasury to fund the Institute and its activities. Monies would be directed to this fund from the general fund of the Treasury, the Medicare Trust Funds, from funds directed to the Secretary by ARRA, and from fees levied on Medicare and privately insured beneficiaries. In FY2013, the amount for Medicare beneficiaries would be $1 per beneficiary; in FY2014 through FY2019, the amount would be equivalent to $2 per beneficiary, increased by annual medical inflation after FY2014. The PCORTF would also be financed from fees on insured and self-insured health plans of $1 per beneficiary in FY2013 and $2 per beneficiary (updated by the rate of medical inflation in FY2014 and in subsequent years) in FY2014 through FY2019. Those fees would sunset after FY2019.

Sec. 3502. Coordination with Federal Coordinating Council for Comparative Effectiveness Research

This section would give FCCCER additional responsibilities with respect to the new Patient-Centered Outcomes Research Institute established in Sec. 3501. FCCCER would be required to

provide support to the Institute and would coordinate with the Institute in carrying out its duties under this section.

Medicare and Medicaid Nursing Homes and other Long Term Care Facilities

Secs. 4201-4221. Improving Transparency, Enforcement, and Staff Training

These sections include a number of provisions that would enhance certain accountability requirements for Medicare certified skilled nursing facility (SNF) and Medicaid certified nursing facility (NF). The changes in these sections would require SNFs and NFs to maintain and make available additional information on facility ownership and organizational structure, as well as to establish new staff compliance and ethics training programs. The changes in these sections also would require the Secretary to establish additional requirements for SNFs and NFs to develop and implement compliance and ethics programs.

The Secretary would further be required to enhance the SNF and NF information available on the Medicare Nursing Home Compare website, and to ensure that information is prominent, easily accessible, searchable, and readily understandable to long-term care consumers. In consultation with experts, the Secretary would be required to establish wage and benefit reporting requirements on Medicare cost reports for SNFs. The Secretary would be required to develop a new standardized complaint form that facilities and states would be required to make available to all stakeholders and consumers. The changes in these sections would require SNFs and NFs to electronically report direct staffing information to the Secretary following specifications the Secretary would establish in consultation with stakeholders. The Government Accountability Office (GAO) would be required to conduct a study of the Centers for Medicare & Medicaid Services Five-Star rating system.

Additional civil money penalties would be established that both the Secretary and states could impose on SNFs or NFs found to have quality of care issues and other deficiencies that jeopardized residents' safety. The Secretary would be required to develop, test, and implement a national independent monitoring program for large interstate and intrastate SNF and NF chains. These sections would establish new requirements for SNF and NF administrators to inform residents and their representatives, as well as the Secretary, states, and other stakeholders of planned facility closures. The Secretary also would be required to conduct demonstration projects on best practices for culture change and use of information technology in SNFs and NFs. Finally, the changes in these sections would require the Secretary to revise initial nurse aide training, competency, and evaluation requirements to include dementia and abuse prevention. The Secretary also could revise dementia management training and patient abuse prevention in ongoing nurse training, competency, and evaluation requirements.

Sec. 4301. Nationwide Program for National and State Background Checks on Direct Patient Access Employees of Long-term Care Facilities and Providers

This section would require the Secretary to establish a nationwide program for national and state background checks on direct patient access employees of certain long-term care (LTC) facilities or providers and provide federal matching funds to states to conduct these activities. The Secretary would be required to carry out the nationwide program under similar terms and conditions as the Background Check Pilot program under Section 307 of the Medicare Prescription Drug, Improvement, and Modernization Act (MMA) of 2003 (P.L. 108-173) which

established the framework for such a program. From January of 2005 through September of 2007, CMS administered the Background Check Pilot program, in consultation with the Department of Justice (DoJ), in seven states (Alaska, Idaho, Illinois, Michigan, Nevada, New Mexico, and Wisconsin) selected to participate.

Under the nationwide program, the Secretary would be required to enter into agreements with newly participating states and previously participating states. Certain LTC providers would be required to obtain state and national criminal history background checks on their prospective employees as the Secretary determines appropriate, efficient, and effective. The section would require the Secretary of the Treasury to transfer to HHS an amount specified by the HHS Secretary as necessary (not to exceed $160 million) to carry out the nationwide program for fiscal years 2010 through 2012. Such amounts would be required to remain available until expended. The Secretary would be authorized to reserve no more than $3 million of the amount transferred to conduct the evaluation.

Health Information Technology

Electronic Health Records (EHRs)

Congress enacted the HITECH Act as part of ARRA to promote the widespread adoption of interoperable EHRs. Among its provisions, the HITECH Act authorized Medicare and Medicaid bonus payments for eligible professionals and hospitals participating in these programs as an incentive to become meaningful users of certified EHR systems. The HITECH Act defines meaningful use to include using certified EHR technology for the purpose of exchanging clinical information to improve the coordination and quality of care, and using such technology to report clinical quality measures. For the Medicare incentives, an eligible professional means a physician, dentist, podiatrist, optometrist, or chiropractor. For the Medicaid incentives, an eligible professional is defined as (1) a non-hospital physician, dentist, certified nurse mid-wife or nurse practitioner with at least a 30% Medicaid patient volume (pediatricians must have at least a 20% Medicaid patient volume); (2) physician assistants that meet certain specified requirements; and (3) FQHCs and rural health clinics with at least a 30% patient volume made up of needy individuals, as defined.

Free clinics are tax-exempt, safety-net health care organizations, staffed by volunteers, that provide a range of medical, dental, pharmacy, and/or behavioral health services to economically disadvantaged individuals who are predominately uninsured. They do not bill Medicare, Medicaid, or private payers for the health care services they provide.

S. 1796 includes two EHR provisions. The first provision would require the Secretary to examine how private health insurers can incentivize meaningful EHR use among providers, and the second is intended to extend eligibility for the Medicare and Medicaid EHR incentives to free clinics.

Sec. 1102. Encouraging Meaningful Use of Electronic Health Records

This section would require the Secretary to study methods—including incentive payments and the promotion of low-cost EHR software—that can be used by qualified health benefits plans (QHBPs) offered through a health insurance exchange to encourage meaningful use of EHRs by providers. Within 24 months of enactment, the Secretary would have to submit to Congress a report containing the results of the study, together with recommendations on the feasibility and effectiveness of such payment incentives.

Sec. 3041. Inclusion of Free Clinics as Providers Eligible for Incentives for Adoption and Meaningful Use of Certified EHR Technology

This section would amend the definition of a professional that is eligible to receive Medicare EHR incentives by clarifying that nothing in the provision would prevent a physician furnishing items and services in a free clinic (as defined above) from being considered so eligible. Additionally, it would amend the definition of a professional eligible to receive Medicaid EHR incentives, by clarifying that nothing in the provision would prevent a physician, dentist, certified nurse mid-wife, nurse practitioner, or physician assistant furnishing items and services in a free clinic (as defined above) from being considered so eligible.

Administrative Simplification

To promote the growth of electronic record keeping and claims processing in the nation's health care system, the Health Insurance Portability and Accountability Act's (HIPAA's) Administrative Simplification provisions (**SSA Secs. 1171-1179**) instructed the Secretary to adopt standards for the electronic transmission of routine administrative and financial health care transactions between health care providers and health plans, including data elements and code sets for the transactions. The HIPAA-specified transactions include (1) health claims, and (2) health care payment and remittance advice. A final rule, which adopted standards that were already in widespread use for seven of the nine specified transactions, as well as code sets to be used in those transactions, was published in 2000. The transactions standards included several Accredited Standards Committee X12 (ASC X12) standards for health care transactions. In January 2009, the Secretary published a final rule adopting updated versions of the HIPAA electronic transactions standards to replace the versions currently is use. The compliance deadline for the updated standards is January 1, 2012.

The health care payment and remittance advice transaction is a communication from a health plan to a provider that includes an explanation of the claim and payment for that claim. The HIPAA standard for this transaction (i.e., ASC X12 835) can accommodate an electronic funds transfer (EFT), in which payment is electronically deposited into a designated bank account. EFT is common in the health care sector—health plan contracts often require it—but there is no EFT mandate in federal law for Medicare, Medicaid, or private health insurance.

HIPAA does not mandate that providers conduct the transactions electronically, though health plans increasingly require it. However, providers that elect to submit one or more of the HIPAA transactions electronically must comply with the standard for those transactions. In 2001, Congress enacted the Administrative Simplification Compliance Act, which mandated that Medicare claims be submitted electronically in the HIPAA standard format, with the exception of those from small providers and in other limited circumstances.

HIPAA also instructed the Secretary to adopt unique identifiers for health care providers, health plans, employers, and individuals for use in standard transactions. Unique identifiers for providers and employers have been adopted, while the health plan identifier is still under review. Congress has blocked the development of a unique individual identifier through language added to the annual Labor-HHS appropriations bill.

Sec. 3601. Administrative Simplification

This section would amend **SSA Sec. 1173** to establish a timeline for the development, adoption and implementation of a single set of consensus-based operating rules for each HIPAA transaction for which there is an existing standard, with the goal of creating as much uniformity in the

implementation and use of the transactions standards as possible. Operating rules are defined as the necessary business rules and guidelines for the electronic exchange of information that are not defined by the electronic standards themselves. In adopting the operating rules, the Secretary would rely on the recommendations of a qualified non-profit entity. Also, the section would add EFT for the payment of health claims as a HIPAA transaction and provide for the adoption and enforcement of an EFT standard.

Operating rules for eligibility and health claims status transactions would have to be adopted by July 1, 2011, and take effect by January 1, 2013. Operating rules for claims payment/remittance and EFT would have to be adopted by July 1, 2012, and take effect by January 1, 2014. The Secretary would have to adopt operating rules for the remaining HIPAA transactions, including health claims, plan enrollment and disenrollment, health plan premium payments, and prior authorization and referral, by July 1, 2014, to take effect by January 1, 2016. The Secretary would also be required to establish a committee to biennially review and provide recommendations for updating and improving the HIPAA standards and operating rules.

By December 31, 2013, health plans would be required to file a certification statement with the Secretary that their data and information systems comply with the most current published standards, including the operating rules, for the following transactions: eligibility, health claims status, claims payment/remittance and EFT. By December 31, 2015, health plans would be required to certify to the Secretary that their data and information systems comply with the most current published standards and operating rules for the remaining completed HIPAA transactions. The Secretary would be permitted to designate an outside entity to verify that health plans have met the certification requirements and would have to conduct periodic audits of plans to ensure that they maintain compliance with the standards and operating rules. The section would require the Secretary, no later than April 1, 2014, and annually thereafter, to assess a penalty fee against health plans that fail to meet the certification requirements. The Secretary of the Treasury, acting through the Financial Management Service (FMS), would be responsible for the collection of penalty fees. Unpaid penalty fees would be increased by an interest payment determined in a manner similar to underpayment of income taxes and would be considered debts owed to federal agencies, which may offset and reduce the amount of tax refunds otherwise payable to a health plan.

In addition to the above provisions, the section would amend **SSA Sec. 1862(a)** to require that as of January 1, 2014, no Medicare payment would be made for benefits delivered under Part A or Part B other than by EFT or an electronic remittance in a form specified in the HIPAA payment/remittance advice (i.e., ACS X12 835) standard. It would also require the Secretary, by July 1, 2013, to report to Congress on the extent to which the Medicare and Medicaid programs and the providers that serve beneficiaries under those programs transact electronically in accordance with the HIPAA standards.

Finally, the section would further amend **SSA Sec. 1173** to require the Secretary to issue a rule to establish a unique health plan identifier. The Secretary would be permitted to issue an interim final rule, which would take effect no later than October 1, 2012.

Prevention and Wellness

Background and Issues

Overview

Prevention interventions are of two key types: those provided to individuals in clinical settings (e.g., cancer screenings) and those provided to communities (e.g., smoking cessation ads). Medicare and Medicaid both cover a number of clinical preventive services, and employer-provided "wellness" programs often include both clinical and community preventive services. Evidence suggests that many prevention interventions can improve the health of patients and populations. However, contrary to common belief, clinical preventive services (including certain cancer screenings) may not yield savings for the payer, but rather a net cost.[10]

Current law addresses prevention in several ways, including through (1) support of evidence review processes to determine whether specific prevention interventions are effective; (2) coverage of certain clinical preventive services under Medicare and Medicaid; and (3) regulation of certain employer-provided wellness programs, in order to strike a balance between flexibility and compliance with current federal privacy, civil rights, and other laws.

Beneficiary cost-sharing has been shown to decrease utilization of certain clinical preventive services, in some contexts. For example, reduced beneficiary cost-sharing is recommended in order to increase utilization of screening mammography.[11]

Evidence of the Effectiveness of Preventive Services

The U.S. Preventive Services Task Force (USPSTF), administered by the Agency for Healthcare Research and Quality (AHRQ), is an independent panel of private-sector experts in primary care and prevention that conducts assessments of scientific evidence of the effectiveness of a broad range of clinical preventive services, including screening, counseling, and preventive medications.[12] It provides evidence-based recommendations for the use of preventive services, which may vary depending on age, gender, and risk factors for disease, among other considerations. Services are given a rating of A, B, C, D or an I Statement. Services rated A or B are recommended. For services rated C, the USPSTF makes no recommendation for or against their routine use. For services rated D, the USPSTF recommends against routinely providing the service to asymptomatic patients, based on evidence that the service is not beneficial, and may be harmful. Finally, services rated with an I Statement are deemed to have insufficient evidence to recommend for or against their routine use.

[10] See, for example, Louise B. Russell, "Preventing Chronic Disease: An Important Investment, But Don't Count On Cost Savings," *Health Affairs*, vol. 28, no. 1 (January/February 2009), pp. 42-45; and Congressional Budget Office, *The Budgetary Effects of Expanding Governmental Support for Preventive Care and Wellness Services*, Letter to the Honorable Nathan Deal, August 7, 2009, http://www.cbo.gov/ftpdocs/104xx/doc10492/08-07-Prevention.pdf.

[11] Task Force on Community Preventive Services, "Recommendations for Client- and Provider-directed Interventions to Increase Breast, Cervical, and Colorectal Cancer Screening," American Journal of Preventive Medicine, vol. 35, suppl. 1 (2008), pp. S21-25. See also CDC, http://www.thecommunityguide.org/cancer/screening/client-oriented/ReducingOutOfPocketCosts.html.

[12] See the U.S. Preventive Services Task Force, http://www.ahrq.gov/clinic/uspstfix.htm.

Clinical Preventive Services in Medicare

In general, Medicare law authorizes the Secretary to cover services for the diagnosis and treatment of illness, while coverage of preventive services (i.e., services provided in the absence of symptoms) has generally required legislation. Section 1861 of the SSA requires coverage of a number of specified preventive services under Medicare Part B. Medicare Advantage (Part C) is an alternative way for Medicare beneficiaries to receive covered services, where private health plans are paid a per-person amount to provide all Medicare-covered benefits to beneficiaries who enroll in their plan.[13] There is no definition of "preventive services" in the law that refers to them collectively. The SSA outlines specific coverage criteria for many preventive services, including factors such as the types of screening tests covered, and the age or risk profiles to which a service applies. Also, in the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA, P.L. 110-275), Congress provided administrative authority for the Secretary to add coverage of additional preventive services, if, among other things, such a service is recommended (i.e., with a grade of A or B) by the USPSTF. Under current law, applicable cost-sharing would apply.

Although the Secretary has the authority to add additional preventive services under the MIPPA provision, the Secretary is not authorized to modify any statutory criteria for the coverage of currently authorized preventive services. Such criteria do not always comport with current USPSTF recommendations regarding the use of these services.

In addition to the preventive services enumerated in law, Medicare covers a one-time initial preventive physical examination (IPPE), with no deductible, with the goal of health promotion and disease detection, to include education, counseling, and referral with respect to screening and other preventive services. The IPPE is reimbursable only if provided within one year of Medicare Part B enrollment. Medicare does not otherwise cover periodic routine health examinations (i.e., those provided in the absence of symptoms).

Section 1833(a) of the SSA establishes coinsurance for the beneficiary, generally requiring Medicare to cover 80% of the costs of covered services under Part B, with specified exceptions. Section 1833(b) establishes an annual deductible for which the beneficiary is responsible. These sections have been amended over the years to waive coinsurance and/or the deductible for many, but not all, covered preventive services.

Medicare coverage of vaccines and their administration has been established in statute. Section 1861(s) of the SSA provides Medicare Part B coverage of three vaccines and their administration: influenza (since 1993), pneumococcal (since 1980), and, for individuals at increased risk, hepatitis B (since 1984). The Medicare Modernization Act of 2003 (MMA, P.L. 108-173) provided coverage under Part D for any other vaccine (including its administration) that is licensed by the FDA (under Section 351 of the PHSA), when prescribed by a physician.

Medicare Advantage (MA, Medicare Part C) participating plans are required to cover all services covered by traditional Medicare; however, they may also offer coverage of additional services. MA plans cover some preventive services that traditional Medicare does not, and cost sharing may be less for such services.[14] In general, cost sharing is lower in MA plans, and more services are covered; this is offset by both beneficiary premiums and plan savings. Cost sharing per enrollee (excluding premiums) for covered services cannot be more than the actuarial value of the

[13] Please see CRS Report R40374, *Medicare Advantage*, by Paulette C. Morgan.

[14] Gold, M. "Medicare Advantage Benefit Design: What Does It Provide, What Doesn't It Provide, and Should Standards Apply?" March 2009. Accessed at http://assets.aarp.org/rgcenter/health/2009_03_medicare.pdf on October 28, 2009.

deductibles, coinsurance, and co-payments under traditional Medicare. However, while the aggregate amount of cost sharing in an MA plan must be equal to the aggregate amount of cost sharing in traditional Medicare, the plan may set different amounts for specific services, such as a lower (or higher) deductible for hospital inpatient services or a lower or waived co-payment for preventive services.[15]

Sec. 2001. Medicare Annual Wellness Visit and Personalized Prevention Plan

Under this section, beginning in 2011, Medicare would cover personalized prevention plan services, including a comprehensive health risk assessment, under Part B. The personalized plan would include specified required elements, among them: review and update of medical and family history; a 5- to 10-year screening schedule and referral for services recommended by the USPSTF; a list of identified risk factors and conditions, and a strategy to address them; and lists of all medications currently prescribed and all providers regularly involved in the patient's care. Additional optional elements could include review or referral for testing and treatment of chronic conditions; cognitive impairment assessment; and administration of or referral for Medicare-covered immunizations and screening tests, among others.

All enrolled beneficiaries would be eligible for personalized prevention plan services once every year, without cost sharing. During the first year of Part B enrollment, beneficiaries could receive either the IPPE or personalized prevention plan services, but not both. Also, all stated required and optional plan elements must be covered for personalized prevention plan services furnished during the first year of enrollment. The Secretary would be required to develop appropriate guidance, and conduct outreach and related activities, with respect to personalized prevention plan services and health risk assessments.

Sec. 2002. Removal of Cost-Sharing for Medicare Preventive Services

This section would amend **SSA Sec. 1861** to define preventive services covered by Medicare to mean a specified list of currently covered services, including colorectal cancer screening services even if diagnostic or treatment services were furnished in connection with the screening. The list would also include the IPPE, as well as the personalized prevention plan services that would be covered pursuant to Sec. 2001 of this bill. Coverage would continue to be subject to all criteria that apply to each preventive service covered under current law.

This section would also amend **SSA Sec. 1833** to waive beneficiary coinsurance requirements for most preventive services, requiring Medicare to cover 100% of the costs. Services for which no coinsurance would be required are the IPPE, personalized prevention plan services, any additional preventive service covered under the Secretary's administrative authority, and any currently covered preventive service (including medical nutrition therapy, and excluding electrocardiograms) if it is recommended with a grade of A or B by the USPSTF. This section would generally waive the application of the deductible for the same types of preventive services noted above for which coinsurance would be waived. It would not, however, waive the application of the deductible for any additional preventive service covered under the Secretary's administrative authority.

Sec. 2003. Evidence-Based Coverage of Medicare Preventive Services

This section would authorize the Secretary to modify the coverage of any currently covered preventive service (including services included in the IPPE, but not the IPPE itself), to the extent

[15] For more information on MA, please see CRS Report R40374, *Medicare Advantage*, by Paulette C. Morgan.

that the modification is consistent with USPSTF recommendations. This section would also prohibit payment for any currently covered preventive service graded D (i.e., not recommended) by the USPSTF. The enhanced authority and the prohibition would not apply to services furnished for the purposes of diagnosis or treatment (rather than as preventive services furnished to asymptomatic patients). This section would appropriate $15 million to CMS for FY2010, to remain available until expended, for a provider and beneficiary outreach program regarding covered preventive services. This section would also appropriate $2 million for a U.S. Government Accountability Office (GAO) study of the utilization of and payment for Medicare covered preventive services, the use of HIT in coordinating such services, and whether there are barriers to the utilization of these services.

Sec. 2004. GAO Study and Report on Medicare Beneficiary Access to Vaccines

This section would require a GAO study and report to Congress on the impact of the coverage of vaccines under Medicare Part D on access to those vaccines by beneficiaries who are 65 years of age or older. This section would appropriate $1 million for FY2010 for this study.

Sec. 2005. Medicare Demonstration: Incentives for Healthy Lifestyles

This section would require the Secretary to conduct a Medicare demonstration project to test programs that provide incentives to Medicare beneficiaries to reduce their risk of health outcomes associated with lifestyle choices, including smoking, exercise, and diet. The project would deliver evidence-based approaches for tobacco cessation; management of weight, cholesterol, and blood pressure; diabetes prevention or management; falls prevention; and other approaches as determined by the Secretary. It would be subject to specified evaluation and reporting requirements. Any incentives provided to a participating Medicare beneficiary could not be taken into account in determining the beneficiary's eligibility for or amount of benefits under any federal program. To carry out this program, this section would appropriate to CMS $15 million for each of fiscal years 2010 through 2015. Funds would remain available until expended.

Prevention and Wellness Services in Medicaid

States are required under Medicaid to cover a package of "well-child" and preventive service benefits for the majority of eligible children under the age of 21, called the Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) services. For eligible beneficiaries including adults, states are required to cover family planning services and supplies, and certain pregnancy-associated services, including prenatal, delivery and postpartum care, as well as services for conditions that may complicate the pregnancy. Otherwise, state coverage of screening and preventive services for eligible adults is optional. These services (defined in SSA Section 1905(a)(13)) may include "other diagnostic, screening, preventive, and rehabilitative services, including any medical or remedial services (provided in a facility, a home, or other setting) recommended by a physician or other licensed practitioner of the healing arts within the scope of their practice under state law, for the maximum reduction of physical or mental disability and restoration of an individual to the best possible functional level." In addition, states may, but are not required to, cover tobacco cessation services (either drugs or counseling).

With some exceptions, premiums and enrollment fees are generally prohibited under traditional Medicaid. When applicable, nominal amounts for such charges range from roughly $1 to $19 per month, depending on family income. States are also allowed to establish nominal service-related cost-sharing requirements, generally between $0.50 to $3, depending on the cost of the service provided. The Deficit Reduction Act of 2005 (DRA, P.L. 109-171) gave states an option to apply

other, higher premium and cost-sharing obligations to certain Medicaid beneficiaries.[16] As with traditional Medicaid, specific groups (e.g., some children, pregnant women, and individuals with special needs) are exempt from the DRA premium provisions. Likewise, specific services and groups (e.g., some children, pregnant women for pregnancy-related services, individuals receiving hospice care, and residents of certain institutions) are exempt from service-related cost-sharing under both traditional Medicaid and the DRA.

Under the optional Medicaid prescription drug benefit, states are permitted to exclude coverage of 11 drug classes, including barbiturates, benzodiazepines, and smoking cessation products. Medicaid programs may cover tobacco cessation counseling services for pregnant women.

Sec. 2101. Improving Access for Preventive Services for Eligible Adults

Effective in 2013, this section would expand the current Medicaid state option to provide other diagnostic, screening, preventive, and rehabilitation services (as per SSA Section 1905(a)(13)) to include (1) any clinical preventive services assigned a grade of A or B by the USPSTF, and (2) with respect to adults, immunizations recommended by the Advisory Committee on Immunization Practices (ACIP), and their administration.[17] States that elect to cover these additional services and vaccines and prohibit cost-sharing for them would receive the increased federal medical assistance percentage (FMAP) for medical assistance for newly eligible mandatory individuals (as per Section 1601(a)(3)(A) of this bill, excluding the 95% cap on such FMAP), for which an additional one percentage point increase in that FMAP would apply for these services, and for counseling and drug therapy for tobacco cessation use by pregnant women (as added by Section 2102 of this bill, described below).

Sec. 2102. Comprehensive Tobacco Cessation Services for Pregnant Women

Effective in October, 2010, this section would require states to provide Medicaid coverage to pregnant women for counseling and drug therapy for tobacco cessation. Such services would include diagnostic, therapy, and counseling services and drug therapy (including prescription and nonprescription tobacco cessation products approved by the FDA), as recommended by the U.S. Surgeon General (SG), and other services that the Secretary recognizes to be effective for cessation of tobacco use by pregnant women. These services would exclude coverage for drugs or biologicals that are not otherwise covered under Medicaid. States would continue to be allowed to exclude coverage of products used for smoking cessation except in the case of pregnant women. This section would prohibit cost-sharing, under either traditional Medicaid or the DRA option, for counseling and drug therapy, as well as for covered outpatient prescription and non-prescription drugs, provided to or used by pregnant women for tobacco cessation.

Sec. 2103. Medicaid Program: Incentives for Health Lifestyles

This section would require the Secretary to award grants to states to provide incentives for Medicaid beneficiaries to participate in programs providing incentives for healthy lifestyles. Programs must be comprehensive and uniquely suited to address the needs of Medicaid beneficiaries, and have demonstrated effectiveness in managing cholesterol and/or blood pressure, losing weight, quitting smoking, and/or managing or preventing diabetes. Programs may address co-morbidities, such as depression, associated with these conditions. The stated purpose

[16] See CRS Report RS22578, *Medicaid Cost-Sharing Under the Deficit Reduction Act of 2005 (DRA)*, by Elicia J. Herz.

[17] The Advisory Committee on Immunization Practices advises the Secretary and the CDC regarding the use of immunizations to control vaccine-preventable diseases. See CDC, "Advisory Committee on Immunization Practices (ACIP)," http://www.cdc.gov/vaccines/recs/acip/default.htm.

of the initiative is to test approaches that may encourage behavior modification and determine scalable solutions.

This section would appropriate $100 million for the program during a five-year period beginning on January 1, 2011. The Secretary may waive Medicaid requirements relating to statewideness and comparability, and would be required to ensure that a participating state makes the program widely available. A number of outreach, evaluation, and reporting requirements would apply. Any incentives received by a beneficiary could not be taken into account for the purpose of determining eligibility for, or the amount of, benefits under any federally funded program.

Sec. 2105. Funding for Childhood Obesity Demonstration Project

The Children's Health Insurance Program Reauthorization Act of 2009 (CHIPRA , P.L. 111-3) included several provisions designed to improve the quality of care under Medicaid and CHIP. Among other things, the law directed the Secretary to initiate a demonstration to develop a comprehensive and systematic model for reducing child obesity, and authorized the appropriation of $25 million for this purpose for the period of FY2009 through FY2013. This section would replace the authorizing language, instead appropriating $25 million for the period of FY2010 through FY2014.

Sec. 2106. Public Awareness of Preventive and Obesity-Related Services

This section would require the Secretary to provide guidance and relevant information to states and health care providers regarding preventive and obesity-related services that are available to Medicaid enrollees, including obesity screening and counseling for children and adults. Each state would be required to design a public awareness campaign to educate Medicaid enrollees regarding availability and coverage of such services.

Employer-Provided Wellness Programs

As employers and insurers have struggled with rising health care costs, there has been significant interest in reducing these costs by incentivizing health behaviors through wellness programs. These programs take many forms, from providing a gym at the workplace to subsidizing the co-pays of certain medications and linking health care benefits or discounts to certain healthy lifestyles. Wellness programs offered by employers may be subject to a number of federal laws.[18] HIPAA amended the Employee Retirement Income Security Act (ERISA), the PHSA, and the Internal Revenue Code (IRC) to create certain nondiscrimination requirements, which provide, among other things, that a group health plan and a health insurance issuer offering group health coverage may not require an individual to pay a higher premium or contribution than another "similarly situated" participant, based on certain health-related factors such as claims experience, receipt of health care, medical history, genetic information, evidence of insurability, or disability.[19] However, HIPAA clarifies that this requirement "do[es] not prevent a group health plan and a health insurance issuer from establishing premium discounts or rebates or modifying otherwise applicable copayments or deductibles in return for adherence to programs of health

[18] See CRS Report R40661, *Wellness Programs: Selected Legal Issues*, coordinated by Nancy Lee Jones; and CRS Report R40791, *Employer Wellness Programs: Health Reform and the Genetic Information Nondiscrimination Act*, by Amanda K. Sarata.

[19] 29 U.S.C. § 1182(b)(1); 42 U.S.C. § 300gg-1(b)(1); 26 U.S.C. § 9802(b)(1).

promotion and disease prevention [i.e., wellness programs]."[20] The HIPAA wellness program regulations divide wellness programs into two categories.[21] First, if a wellness program provides a reward[22] based solely on participation in a wellness program, or if the wellness program does not provide a reward, the program complies with the HIPAA nondiscrimination requirements without having to satisfy any additional standards, as long as the program is made available to all similarly situated individuals. Second, if the conditions for obtaining a reward under a wellness program are based on an individual meeting a certain standard relating to a health factor, then the program must meet additional requirements.

Sec. 1901. Programs of Health Promotion and Disease Prevention

This section would amend **IRC Sec. 9802(b)** (and, by reference, Sections 2702(b) of the PHSA, and 702(b) of ERISA) to codify and amend provisions of the HIPAA wellness program regulations, which allow group health plans and group health insurance issuers to provide rewards to individuals for participation in or for meeting certain health standards related to a wellness program. Consistent with current regulation, this section indicates that wellness programs that do not require an individual to satisfy a standard related to a health factor as a condition for obtaining a reward (or do not offer a reward) would not violate HIPAA, so long as participation in the programs is made available to all similarly situated individuals. However, if any of the conditions for obtaining a reward under a wellness program are based on an individual meeting a certain standard relating to a health factor, the program must meet additional requirements. Among these requirements, the reward must be capped at 30% of the cost of the employee-only coverage under the plan. However, the Secretaries of HHS, Labor, and the Treasury would have the discretion to increase the reward up to 50% of the cost of coverage if the increase is determined to be appropriate. Further, this type of wellness program must be reasonably designed to promote health or prevent disease. A program complies with this requirement if it has a reasonable chance of improving the health of, or preventing disease in, participating individuals and it is not overly burdensome; is not a subterfuge for discriminating based on a health status factor; and is not highly suspect in the method chosen to promote health or prevent disease.

This section would also apply the provisions described above to carriers providing Federal Employee Health Benefit Program (FEHBP) benefits. This section would require the Secretary of HHS, in consultation with the Secretary of the Treasury, to establish a 10-state pilot program no later than July 1, 2014, in which states would be required to apply the wellness program provisions to health insurers in the individual market. In addition, the Secretary, in consultation with the Secretary of Treasury and the Secretary of Labor, would be required to submit a report to the appropriate committees of Congress.

[20] 29 U.S.C. § 1182(b)(2)(B); 42 USC 300gg-1(b)(2)(B); 26 U.S.C. § 9802(b)(2)(B).

[21] Nondiscrimination and Wellness Programs in Health Coverage in the Group Market, 71 Fed. Reg. 75014 (Dec. 13, 2006).

[22] The regulations provide that a reward can take the form of a discount or rebate of a premium or contribution, a waiver of all or part of a cost-sharing mechanism (e.g., deductibles, copayments, or coinsurance), the absence of a surcharge, or the value of a benefit that would otherwise not be provided under the plan (e.g., a prize). 29 C.F.R. § 2590.702(f)(2)(i); 45 C.F.R. § 146.121(f)(2)(i); 26 C.F.R. § 54.9802-1(f)(2)(i).

Maternal and Child Health Services

Early Childhood Home Visitation

Title V of the SSA authorizes the Maternal and Child Health (MCH) block grant program. The MCH block grant, which is administered by the Health Resources and Services Administration (HRSA), allocates funding to states based on a statutory formula. States use the Title V funds to design and implement a wide range of maternal and child health programs. States must submit annual reports on Title V-funded activities and demonstrate progress made towards standardized MCH status indicators (e.g., live birth rate, low birth weight, maternal death rates, and poverty levels) in order to facilitate comparison between states. The Secretary compiles the data submitted by the states in an annual report to Congress. States are required to audit and report on the use of their funds at least once every two years.

Home visitation is used to deliver support and services to families or individuals in their homes. Early childhood home visitation programs typically seek to improve maternal and child health; early childhood social, emotional, and cognitive development; and family/parent functioning. Depending on the particular model of early home visitation being used, the visitors may be specially trained nurses, other professionals, or paraprofessionals. Visits, which often occur weekly, may begin during a woman's pregnancy or some time after the birth of a child and may continue until the child reaches his/her second birthday (in some cases) or enters kindergarten. Participation of families is voluntary. Early childhood home visitation programs are in operation in all 50 states. In addition to private and state and local public funds provided for early childhood home visitation, a number of federal programs have been tapped to support home visitation programs. Among others, these include Medicaid, the Temporary Assistance for Needy Families block grant, the Social Services Block Grant, Community-Based Grants to Prevent Child Abuse and Neglect, the MCH block grant, Healthy Start, and Early Head Start.[23]

Sec. 1801. Maternal, Infant, and Early Childhood Home Visitation Programs

This section would add a new **SSA Sec. 511**, Early Childhood Home Visitation Programs. The new provision would require states, as a condition for receiving the MCH block grant funds for FY2011, to conduct a needs assessment, separate from but coordinated with the assessments currently required under Title V and the Head Start Act. The needs assessment would identify communities that have (1) concentrations of risk factors for maternal and child health, poverty, crime, domestic violence, high drop-out rates, substance abuse, unemployment and child maltreatment; and (2) few quality home visitation programs—including the number and types of individuals and families receiving services from home visitation programs—and gaps in early childhood home visitation in the state, and the extent to which these programs are meeting the needs of certain eligible families. The needs assessment also would identify the state's capacity for providing substance abuse treatment and counseling services to those in need.

In addition, the section instructs the Secretary to award competitive grants to support early childhood home visitation programs for improving maternal and child health and school readiness, among other factors. Grantees of this new program would be required to establish quantifiable three- and five-year benchmarks for measuring improvements for the eligible families participating in the program in each of the following areas: maternal and child health, childhood injury prevention, school readiness, juvenile delinquency, family economic factors, and

[23] For more information, please see CRS Report R40705, *Home Visitation for Families with Young Children*, by Emilie Stoltzfus and Karen E. Lynch.

coordination with community resources. Grantees that failed to demonstrate improvement in meeting the three-year benchmarks in at least four of the specified areas would have to develop and implement a plan to improve outcomes. Grantees that continued to show a lack of improvement, or that failed to report on benchmarks, could have their grant terminated. By December 31, 2014, the grantees would be required to submit a report to the Secretary demonstrating progress on the three- and five-year benchmarks.

Grantees could use established, evidence-based service delivery models or promising new approaches yet to be rigorously evaluated, though no more than 25% of the award could be used to fund a promising new program model. They would have to give priority to providing services to families who are determined to be at-risk by the needs assessment and other indicators, including low-income, young maternal age, and involvement with child welfare. Grantees would be required to maintain their aggregate spending on home visitation programs at no less than the FY2009 level.

The Secretary would be required: (1) to appoint an expert panel to design an evaluation of the home visitation grants program, including an analysis of the state needs assessments and the impact of early childhood home visitation programs on various child and parent outcomes; and (2) by grant or contract, conduct such an evaluation and report the results to Congress by March 31, 2015. The Secretary also would be required to submit by December 31, 2015, a final report on the activities conducted with funding from this grants program. The report would include information on: (1) the extent to which grantees demonstrated improvement, (2) any technical assistance provided, and (3) recommendations for further legislative or administrative action.

The section would appropriate a total of $1.5 billion between FY2010 and FY2014 for the home visitation grants program: $100 million for FY2010; $250 million for FY2011; $350 million for FY2012; $400 million for FY2013; and $400 million for FY2014. Of the amount appropriated for this program, 3% would be used for research and evaluation, and 3% would be used to provide home visitation services to Indian families. Funds appropriated for this program for a fiscal year would be available to the Secretary until September 30, 2014.

Postpartum Depression

Sec. 1802. Support, Education, and Research for Postpartum Depression

This section would encourage the Secretary to continue specified types of research—including epidemiology, clinical research, and public education—to expand our understanding of the causes and treatments for postpartum depression and related conditions. The section also states that it is the sense of Congress that the Director of the National Institute of Mental Health (NIMH) may conduct a nationally representative longitudinal study (during the period FY2010-FY2019) on the relative mental health consequences for women of resolving a pregnancy, intended and unintended, in various ways (e.g., carrying the pregnancy to term and parenting the child, miscarriage, abortion). Subject to the completion of such a study, beginning within five years of enactment and periodically thereafter for the duration of the study, the NIMH Director may submit to Congress reports on the study's findings.

Additionally, this section would create a new **SSA Sec. 512**, Services to Individuals with a Postpartum Condition and their Families. The new section would authorize the Secretary to award grants, in addition to any other funds that would be provided to states under Title V, to eligible entities to establish, operate and coordinate effective and cost-efficient systems for the delivery of essential services to individuals with postpartum conditions and their families. Grant funds could be used to carry out certain activities such as providing education, delivering outpatient and

home-based services, enhancing inpatient care management, and improving health care and social services. Grantees would have to agree to various requirements, including not using the grant funds to supplant other existing funds or to pay for services that can be paid for by certain other payers.

Eligible entities include public or nonprofit private entities, state or local government public-private partnerships, recipients of Healthy Start grants, public or nonprofit private hospitals, community-based organizations, hospices, ambulatory care facilities, CHCs, migrant health centers, public housing, primary care centers, and homeless health centers. The section would authorize the appropriation of $3 million for FY2010, and SSAN for FY2011 and FY2012 to carry out the grant program. The Secretary would be required to study the benefits of screening for postpartum conditions and, within two years of enactment, submit a report to Congress. Finally, the Secretary would be prohibited from using funds under this section to duplicate any other HHS activities or programs.

Personal Responsibility and Abstinence Education

PHSA Title XX, Adolescent Family Life Demonstration Projects, authorizes a number of voluntary teen pregnancy prevention, counseling, and related programs. The Secretary may award demonstration grants to public or nonprofit private entities to provide care and/or prevention services (including educational services) according to specified requirements. Grantees are required to evaluate program results and report to the Secretary, and the Secretary is authorized to support research on teen pregnancy prevention. PHSA Title X, Population Research and Voluntary Family Planning Programs, authorizes grants for comprehensive voluntary family planning services, education, and research, including such activities regarding adolescents. PHSA Sections 318 and 318A authorize grants for technical assistance and voluntary services (including screening, treatment, counseling, and education) to address sexually-transmitted diseases in women. These provisions do not explicitly address adolescents.

SSA Sec. 510 authorizes a state formula grant program to support abstinence education programs. Funds are awarded to states based on the number of low-income children in each state, and may only be used for teaching abstinence. To receive funding, a state must match every $4 in federal funds with $3 in state funds. Sec. 510 provided $50 million for each of five years (FY1998-FY2002). Although the program has not been reauthorized, the latest of several extensions, included in the Medicare Improvements for Patients and Providers Act of 2008, continued funding through June 30, 2009.[24]

Sec. 1803. Personal Responsibility Education for Adulthood Training

This section would add a new **PHSA Sec. 513**, Personal Responsibility Education for Adulthood (Pre-Adulthood) Training. The new section would establish a state formula grant program for FY2010 through FY2014 to fund evidence-based, age- and culture-appropriate education programs on (1) abstinence and contraception, and (2) adulthood preparation topics such as healthy relationships, adolescent development, financial literacy, parent-child communication, educational and career success, and healthy life skills. Under the funding allocation formula, each state would receive an amount based on the size of its youth population age 10-19 as a percentage of the national population of such individuals. However, each state would receive a minimum allotment of at least $250,000 for the fiscal year.

[24] For more information, see CRS Report RS20873, *Reducing Teen Pregnancy: Adolescent Family Life and Abstinence Education Programs*, by Carmen Solomon-Fears.

States that do not apply for funds in FY2010 and FY2011 would not be eligible to apply for the funds allotted for the period FY2010 through FY2014. The Secretary would be required to use unexpended funds resulting from states not submitting an application, or states not expending their allocation, to award three-year grants to local organizations in each of FY2012, FY2013 and FY2014, for use as required in states that do not apply for the allocations. The Secretary would be allowed to solicit applications from faith-based organizations or consortia.

The Secretary would be required to use some of the funds appropriated to carry out this section for the following purposes. First, of the appropriated funds $10 million would be used for grants to implement innovative teen pregnancy prevention strategies and target services to high-risk youth populations. Second, 5% of the remaining funds would be used to award grants to Indian tribes and tribal organizations. Third, 10% of the remaining funds would be used (1) to establish a national teen pregnancy prevention resource center, (2) to conduct research on, and provide training and technical assistance for, the programs and activities funded under this section, and (3) to evaluate the programs and activities funded under this section.

There would be appropriated $75 million for each of FY2010 through FY2014 to carry out this section. Amounts appropriated would remain available until expended.

Sec. 1804. Abstinence Education

This section would amend **SSA Sec. 510** by appropriating $50 million for each of FY2010 through FY2014 for the abstinence education grant program.

Health Disparities

Data on Health Disparities

Federal initiatives such as the National Healthcare Disparities Report (NHDR)[25] and HealthyPeople 2010[26] examine health status, access to care, quality of care, and health disparities for the nation as a whole and for population subgroups. These initiatives depend mainly on existing federally sponsored data. The Office of Management and Budget (OMB) issues statistical policy guidance for the collection of data from federally sponsored surveys, administrative forms and other records and, in 1997, issued "Revisions to the Standards for the Classification of Federal Data on Race and Ethnicity." These standards revised and superseded previous guidance, referred to as Statistical Policy Directive No. 15 (or Directive 15).[27] OMB provided further provisional guidance on implementation of the new standards in 2000[28]. The 1997 revised standards and 2000 provisional guidance established that data on race and ethnicity should be collected using:

- an ethnicity question (Hispanic or Latino vs. Not Hispanic or Latino);

[25] U.S. Department of Health and Human Services, Agency for Healthcare Research and Quality. 2008 National Healthcare Disparities Report. AHRQ Publication No. 09-001. March 2009. http://www.ahrq.gov/qual/nhqr08/nhqr08.pdf

[26] HealthyPeople 2010 Fact Sheet. http://www.healthypeople.gov/About/hpfact.htm

[27] Revisions to the Standards for the Classification of Federal Data on Race and Ethnicity; *Federal Register*, Thursday October 30, 1997, pp. 58782. http://www.whitehouse.gov/omb/fedreg_1997standards/

[28] Provisional Guidance on the Implementation of the 1997 Standards for Federal Data on Race and Ethnicity December 15, 2000. http://www.whitehouse.gov/omb/assets/information_and_regulatory_affairs/re_guidance2000update.pdf.

- a five category race item (White, Black or African American, American Indian or Alaska Native, Asian, and Native Hawaiian or other Pacific Islander); and
- within the race item, a requirement that respondents be offered the option of selecting one or more races.

The revised standards were applied to the 2000 decennial census and federal agencies were advised to adopt the standards as soon as possible, but not later than January 1, 2003 for household surveys, administrative forms and records, and other data collections. The 2000 provisional guidance was designed to facilitate implementation of the standards, and included discussion of data tabulation and procedures for building bridges to compare data collected under the 1997 and 1977 (Directive 15) standards.

Agency data collection efforts may use categories beyond this minimum set (for example, collect information on Hispanic subpopulations); however, categories must be aggregated into the established minimum set for reporting purposes. A third OMB guidance document, also issued in 2000, addressed how to allocate multiple race responses to the categories established in the 1997 standards for civil rights monitoring and enforcement.[29]

OMB standards do not apply to state and municipal public health departments or to Medicaid. While the standards do apply to CHIP, they are not binding on states that opt to use CHIP funding to finance a Medicaid expansion or that employ a combined approach. The standards may be waived under special circumstances, and through a specific request from OMB.

The OMB standards do not address primary language; however, CMS mandates that this information be reported for Medicaid beneficiaries. CMS does not require the collection of primary language data from CHIP enrollees, their parents or legal guardians.

Current law does not require the collection of data on access to care for disabled individuals for any federal health care program or other federally sponsored entities. Data on access to care by the disabled are collected in federally sponsored surveys such as the National Health Interview Survey, the Medical Expenditure Panel Survey, the Behavioral Risk Factor Surveillance System, and the Medicare Current Beneficiary Survey; however, analysis of survey data is limited by the number and type of survey items included, variation in the items across surveys, and limitations in the sample and sample size for individuals with disabilities.

Sec. 1701. Standardized Collection of Data

This section would require the Secretary to establish procedures to ensure that all data collected on race, ethnicity, sex, and primary language under federal and state health care programs does so in compliance with OMB Directive 15; OMB guidance for federal agencies that collect or use aggregate data on race; and OMB guidance for federal agencies for the allocation of multiple race responses for use in civil rights monitoring and enforcement. This section would also require the Secretary to establish procedures for the CMS Administrator to collect data under federal and state health care programs to assess access to care and treatment for individuals with disabilities. Such procedures would include surveying health care providers to identify where people with disabilities receive primary, acute and long-term care; the number of providers with accessible

[29] "Guidance on Aggregation and Allocation of Multiple Race Responses for Use in Civil Rights Monitoring and Enforcement". OMB Bulletin No. 00-02. March 9, 2000. http://www.whitehouse.gov/omb/bulletins_b00-02/.

facilities and equipment; and the number of health care provider employees trained in disability awareness and in caring for patients with disabilities.[30]

Required Collection of Data

Many federal data collection efforts include items for measuring race and ethnicity or subpopulations such as those whose primary language is not English or persons with disabilities; however, sample surveys are often of insufficient sample size to ensure reliable estimates with appropriate precision for small subpopulations. Sample size also influences the level of analysis that can be conducted; for example, larger sample sizes may be needed to study a specific medical condition among subgroups of a population. Some surveys use oversampling to increase the precision of subpopulation estimates. Other times, data from multiple years are combined to produce stable estimates. The need for and size of a sample is tied, in part, to the cost of the data collection effort.

Current law requires the evaluation of data collection approaches under Medicare that facilitate the collection and evaluation of disparities data. In addition, the Secretary is required to develop reports for Congress identifying best approaches for the collection of disparities data and recommending ways to improve the care delivered to Medicare beneficiaries based on the analysis of disparities data.

Sec. 1702. Required Collection of Data

This section would require that federally funded population surveys collect sufficient data relating to race, ethnicity, sex, primary language, and type of disability to generate statistically reliable estimates in studies comparing health disparities among populations. It would ensure that quality reporting requirements under federal health care programs would include the collection of data on individuals receiving health care items or services under these programs by race, ethnicity, sex, primary language, and type of disability.

This section would add a new **SSA Sec. 1945, "Addressing Health Care Disparities,"** which would require the Secretary to evaluate approaches for the collection of data that allow for the collection and evaluation of data on health care disparities. In conducting this evaluation, the Secretary would be required to consider several objectives, including protecting patient privacy, minimizing the administrative burden of data collection and reporting, and improving program data on race, ethnicity, sex, primary language, and type of disability. This new section would require the Secretary to submit a report on the evaluation of data collection methodologies conducted pursuant to this section, and would include approaches for identifying, collecting, and evaluating health disparities data under Medicaid and CHIP. The Secretary would also be required to submit a series of reports that would include recommendations for improving the identification of health disparities for Medicaid and CHIP beneficiaries. Finally, this section would require the Secretary to implement the data collection approaches identified under this section for the collection and evaluation of health disparities data within 24 months after the date of enactment of this Act.

[30] This section would apply to any Federal health care program, funded directly, in whole or in part, by the United States Government, as well as state health care programs (Title XIX, Medicaid; Title V, the Maternal Child Health Services Block Grant program; Title XX, block grants to states for social services; Title XXI, Children's Health Insurance Program). It would apply to any plan or program that provides health benefits, whether directly, through insurance, or otherwise.

Data Sharing

HHS is actively engaged in facilitating data sharing through efforts such as HealthyPeople 2010, the NHDR, the HHS Data Council, and other efforts.

Several current laws pertain to the privacy and protection of health data. The Privacy Act of 1974 (P.L., 93-579) established a code of fair information practices that governs the collection, maintenance, use, and dissemination of personally identifiable information about individuals that is maintained in systems of records by federal agencies. The Privacy Act prohibits the disclosure of information from a system of records absent the written consent of the individual, unless the disclosure is pursuant to one of 12 statutory exceptions. The Privacy Act also provides individuals with a means to seek access to, and amendment of, their records and sets forth various agency record-keeping requirements.

HIPAA protects individually identifiable health data acquired, used, and maintained by federal programs such as Medicare and Medicaid, which meet the law's definition of a health care provider or health plan. The HIPAA privacy rule places limitations on the use and disclosure of personal health information without patient authorization. The HIPAA security standards specify certain administrative, physical, and technical measures to safeguard health information in electronic form against unauthorized access, use, and disclosure.

In addition, OMB has promulgated guidance for Title V of the E-Government Act, Confidential Information Protection and Statistical Efficiency Act of 2002 (CIPSEA), which provides a uniform policy for federal statistical collections that facilitates comparability of data collected and sets principles and requirements for safeguarding confidential information acquired under statistical collections.

Sec. 1703. Data Sharing and Protection

This section would require the Secretary to establish procedures for sharing data collected under a federal health care or insurance program on race, ethnicity, gender, primary language, and type of disability, and relevant analyses of such data, with other federal and state agencies, as well as agencies within HHS. This section would also require the Secretary to ensure all appropriate privacy and security safeguards are followed for the collection, analysis, and sharing of these data.

Emergency Care

Background and Issues

PHSA Title XXVIII, Subtitle B established the Office of the Assistant Secretary for Preparedness and Response (ASPR). The Office advises the HHS Secretary on matters related to bioterrorism and other public health emergencies, and coordinates medical incident response assets and activities, among other functions. The Emergency Care Coordination Center (ECCC), a new strategic office established in January 2009 and located within ASPR, is coordinating federal government efforts to improve the nation's system of emergency medical care delivery.

The Emergency Medical Treatment and Labor Act (EMTALA; SSA Sec. 1867) requires hospital emergency departments to examine and treat any individual who comes to the hospital with an emergency medical condition, and any woman who is in labor. EMTALA further requires hospitals to offer treatment, within their capacity and with the individual's consent, to stabilize the emergency condition, or transfer the individual to another medical facility, subject to certain

restrictions. EMTALA does not preempt state or local laws unless they directly conflict with its specific requirements. In addition, EMTALA prohibits discrimination and delay in examining or treating emergency patients, and provides protections to whistleblowers who report violations of its provisions.

Many trauma experts consider the first 60 minutes after an injury to be a so-called "golden hour" when trauma care is most effective in saving lives. Given that the risk of death for severely injured patients rises significantly after one hour, trauma systems strive to offer access within that time period, from receipt of the initial emergency call to arrival at a trauma center. The geographic distribution of trauma centers varies widely across states and regions. Many areas of the country are not well served by trauma centers, while other areas may have a surplus of centers, possibly leading to inefficiencies, lower patient volumes per center, and reduced quality of care. More than 84% of U.S. residents can reach level I or II trauma center within an hour, but access lags in rural areas.[31]

Sec. 3116. Working Group on Access to Emergency Medical Care

This section would require the Secretary, within 60 days of enactment, to establish a Working Group on Access to Emergency Medical Care. The Working Group would include representatives of emergency medical personnel, public officials, advocates and emergency care hospitals and health systems, who would serve without compensation. HHS would be required to provide administrative support, technical assistance and the use of facilities.

Duties of the Working Group would include identifying and examining: (1) barriers causing delays in timely inpatient admission of certain patients who present at emergency departments; (2) factors in the health care delivery, financing, and legal systems that impede or prevent the effective delivery of emergency department services, as required under EMTALA; and (3) best practices to improve patient flow within hospitals. The Working Group would be required to develop recommendations for admission, boarding and diversion standards. It would also be required to develop guidelines, measures and incentives to ensure proper implementation, monitoring and enforcement of the standards.

The Working Group would be required to submit its recommendations to Congress and the Secretary and would terminate upon submission of the report.

Health Care for Veterans

Background and Issues

The Department of Veterans Affairs (VA), through the Veterans Health Administration (VHA) operates the nation's largest integrated direct health care delivery system.[32] While Medicare, Medicaid, and the Children's Health Insurance Program (CHIP) are also publicly funded programs, most health care services under these programs are delivered by private providers in private facilities. In contrast, the VA health care system is a truly public health care system in the

[31] Charles C. Branas, *No Time to Spare: Improving Access to Trauma Care*, University of Pennsylvania, Leonard David Institute of Health Economics, September 2005, http://www.upenn.edu/ldi/issuebrief11_1.pdf.

[32] U.S. Department of Veterans Affairs, *FY 2008 Performance and Accountability Report*, Washington, DC, November 17, 2008, p. 10; Established on January 3, 1946 as the Department of Medicine and Surgery by P.L. 79-293, succeeded in 1989 by the Veterans Health Services and Research Administration, renamed the Veterans Health Administration in 1991.

sense that the federal government owns the medical facilities and employs the health care providers.[33]

In general, eligibility for VA health care is based on veteran status,[34] service-connected disabilities[35] or exposures,[36] income,[37] and other factors such as veterans who were former prisoners of war (POW) or who are awarded the Purple Heart.[38]

The VHA pays for care provided to veterans by private-sector providers on a fee basis under certain circumstances. Inpatient and outpatient care are also provided in the private sector to eligible dependents of veterans under the Civilian Health and Medical Program of the Department of Veterans Affairs (CHAMPVA).[39] All enrolled veterans are offered a standard medical benefits package.[40]

Veterans do not pay premiums or enrollment fees. However, under current law most veterans are required to pay copayments for the treatment of nonservice-connected conditions.[41] Those veterans who are rated 50% or more service-connected disabled and enrolled in the VA health care system do not pay copayments even for nonservice-connected care. VA is required to collect reasonable charges for medical care or services (including prescription drugs) from a third party insurer to the extent that the veteran or the provider of the care or services would be eligible to receive payment from a third party insurer for a nonservice-connected disability for which the veteran is entitled to care (or the payment of expenses of care) under a health insurance plan.[42]

Sec. 1922. Protection of Access to Quality Health Care through the Department of Veterans Affairs and the Department of Defense

This section provides that nothing in the bill would prohibit or penalize veterans, or their eligible family members (CHAMPVA beneficiaries), from receiving timely access to quality health care from the VA health care system or a contracted health care provider.

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[33] U.S. Congress, House, *Economic Report of the President*, 110th Cong., 2nd sess., February 2008, H. Doc. 110-83 (Washington: GPO, 2008), p. 106.

[34] Veteran's status is established by active-duty status in the U.S. Armed Forces, and an honorable discharge or release from active military service. Generally, persons enlisting in one of the armed forces after September 7, 1980, and officers commissioned after October 16, 1981, must have completed two years of active duty or the full period of their initial service obligation to be eligible for VA health care benefits. Servicemembers discharged at any time because of service-connected disabilities are not held to this requirement.

[35] A service-connected disability is a disability that was incurred or aggravated in the line of duty in the U.S. Armed Forces (38 U.S.C. § 101 (16). VA determines whether veterans have service-connected disabilities, and for those with such disabilities, assigns ratings from 0% to 100% based on the severity of the disability. Percentages are assigned in increments of 10% (38 C.F.R. §§ 4.1-4.31).

[36] For example, veterans who may have been exposed to Agent Orange during the Vietnam War or veterans who may have diseases potentially related to service in the Gulf War may be eligible to receive care.

[37] Veterans with no service-connected conditions and who are Medicaid eligible, or who have an income below a certain VA means-test threshold and below a median income threshold for the geographic area in which they live are also eligible to enroll in the VA health care system.

[38] For a complete discussion on eligibility for VA health care, priority groups, and enrollment see, CRS Report R40737, *Veterans Medical Care: FY2010 Appropriations*, by Sidath Viranga Panangala.

[39] For further information on CHAMPVA, see CRS Report RS22483, *Health Care for Dependents and Survivors of Veterans*, by Sidath Viranga Panangala.

[40] A detailed listing of VHA's standardized medical benefits package is available at 38 C.F.R. § 17.38 (2008).

[41] 38 U.S.C. § 1729.

[42] 38 U.S.C. § 1729(a)(2)(D); 38 C.F.R. § 17.101(a)(1)(i).

Sec. 6011. Study and Report on Effect on Veteran's Health Care

This section would require the Secretary of Veterans Affairs to conduct a study on the effect of Secs. 6008 and 6009 in Title VI of S. 1796 on the cost of medical care provided to veterans, and veterans' access to medical devices and branded prescription drugs. The Secretary would be required to report the results of such a study to the House Committee on Ways and Means and the Senate Finance Committee. An initial report would be required by December 31, 2012, and the final report would be required by December 31, 2015.[43]

Elder Justice

Background and Issues

Abuse, neglect, and exploitation of older individuals in domestic and institutional settings, such as nursing homes, affects hundreds of thousands of older Americans every year according to national experts. Precisely how many older individuals are mistreated by someone on whom they depend for care or protection is unknown and there are no national statistics on the issue. However, some evidence and anecdotal reports indicate that the problem is serious and that many incidents are never reported.[44]

Efforts to collect data on elder abuse, neglect, and exploitation at the national level pose several problems, including variation in state statutory definitions of elder abuse that make it difficult to identify actions that constitute abuse and neglect and a lack of a uniform reporting system across states. In the absence of national data on the issue policymakers have relied on independent research studies to shed light on the magnitude of the problem. The most recent study to estimate the occurrence of elder abuse and neglect nationally, estimated that about 450,000 persons age 60 or older experienced abuse or neglect in domestic settings in 1996.[45] In 2003, a National Research Council Study estimated that between 1 and 2 million Americans age 65 and older had been injured, exploited, or mistreated.[46]

Congressional interest in the issue of elder abuse, neglect, and exploitation spans more than a quarter of a century. The first hearings on the topic of elder abuse in domestic settings were held jointly by the U.S. Senate and House Committees on Aging in June of 1980. Congress has addressed the issue of abuse in institutional settings since, at least, the early 1960's when the Senate Special Committee on Aging initiated its first investigations. Since then numerous hearings and Congressional reports have been authored concerning the need for a federal response to abuse, neglect, and exploitation of the elderly. As a result, Congress has implemented modest reforms, including federal assistance to state Adult Protective Services programs through the Social Security Block Grant (SSBG) and amendments to the Older Americans Act to provide separate funding for elder abuse prevention and vulnerable elder rights protection activities, including establishment of the Long-Term Care Ombudsman Program. While Congress has

[43] This section has been included to study any adverse effects of fees charged to drug and device manufactures on VA health care.

[44] Richard J. Bonnie and Robert B. Wallace, eds., *Elder Mistreatment: Abuse, Neglect and Exploitation in an Aging America*, National Research Council of the National Academies, National Academy Press, Washington, DC, 2003.

[45] National Center on Elder Abuse at American Public Human Services Association, *National Elder Abuse Incidence Study*, prepared for the U.S. Department of Health and Human Services. The Administration for Children and Families and the Administration on Aging, Washington, DC, 1998.

[46] Richard J. Bonnie and Robert B. Wallace, eds., *Elder Mistreatment: Abuse, Neglect and Exploitation in an Aging America*, National Research Council of the National Academies, National Academy Press, Washington, DC, 2003.

enacted comprehensive legislation to address child abuse and neglect under the Child Abuse Prevention and Treatment Act (CAPTA) (P.L. 93-247) in 1974 and domestic violence under the Violence Against Women's Act (VAWA) of 1994, legislation addressing abuse, neglect, and exploitation of the elderly at a national level has not been enacted.

Recognizing the need for a coordinated federal effort with a multidisciplinary approach that combines law enforcement, public health, and social services to combat abuse, neglect, and exploitation of the elderly, Congress first introduced the Elder Justice Act of 2002 (S. 2933) in the 107th Congress by then Senator John Breaux. The Elder Justice Act represents Congress' attempt at comprehensive legislation on this issue. Similar measures were introduced in both the Senate and the House in the 108th (S. 333; H.R. 2490), 109th Congress (S. 2010; H.R. 4993), and 110th Congresses (S. 1070; H.R. 1783). Provisions regarding elder justice were also incorporated in the 2006 reauthorization of the Older Americans Act (OAA) of 1965 (P.L. 109-365). In the 111th Congress, Senator Orrin Hatch introduced the Elder Justice Act of 2009 (S. 795) on April 2, 2009, a companion bill (H.R. 2006) was introduced in the House by Representative Peter T. King. Elder justice provisions in S. 795 were incorporated into the Senate Finance Committee's health reform bill (S. 1796). The following summarizes these key provisions in this bill.

Sec. 1913. Elder Justice

This section includes the following provisions divided into three subsections: (a) elder justice provisions amended to Title XX of the SSA; (b) various provisions related to protecting residents of long-term care facilities; and (c) establishing a national nurse aide registry.

Elder Justice

Subsection (a) of Sec. 1913 would amend Title XX of the SSA to insert new "Elder Justice" provisions to a newly entitled "Block Grants to States for Social Services and Elder Justice." This section would insert a new "Subtitle A—Block Grants to States for Social Services" before Section 2001 of the SSA and add new sections with various Elder Justice provisions under a new "Subtitle B—Elder Justice." The Elder Justice provisions under Subtitle B would be composed of two parts: "Part I—National Coordination of Elder Justice Activities and Research" and "Part II—Programs to Promote Elder Justice."

Part I—National Coordination of Elder Justice Activities and Research

The proposed Title XX, Subtitle B, Part I would be divided into two subparts—**Subpart A** would establish an Elder Justice Coordinating Council and Advisory Board on Elder Abuse, Neglect, and Exploitation comprised of new Secs. 2021-2024; **Subpart B** would add a new Sec. 2025 awarding grants to establish and operate stationary and mobile forensic centers. These sections and activities are described in further detail below.

Subpart A—Elder Justice Coordinating Council and Advisory Board on Elder Abuse, Neglect, and Exploitation. Subpart A would add a new **Sec. 2021** "Elder Justice Coordinating Council" to be established in the Office of the Secretary of HHS. The Council would include the HHS Secretary who would chair the Council and the Attorney General as well as the head of each federal department or agency, identified by the Chair, as having administrative responsibility or administering programs related to elder abuse, neglect, and exploitation. The Council would be required to make recommendations to the Secretary regarding coordination of activities of HHS, DoJ, and other relevant Federal, state, local, and private agencies and entities, relating to prevention of elder abuse, neglect, and exploitation and other crimes against elders. The Council would be required to submit a report to the appropriate committees of Congress within two years of enactment and every two years thereafter that describes its activities and challenges; and make

recommendations for legislation, model laws, and other actions deemed appropriate. There would be authorized to be appropriated SSAN to carry out the Council's functions.

Subpart A would also add a new **Sec. 2022** "Advisory Board on Elder Abuse, Neglect and Exploitation" establishing an Advisory Board to create a short- and long-term multidisciplinary plan for development of the field of elder justice and make recommendations to the Elder Justice Coordinating Council. The Advisory Board would be composed of 27 members from the general public appointed by the Secretary to serve for staggered three-year terms, and must have experience and expertise in prevention of elder abuse, neglect, and exploitation. The Advisory Board would be required to develop collaborative approaches to improving the quality of LTC and to establish multidisciplinary panels to address these subjects by examining relevant research and identifying best practices, among other things. There would be authorized to be appropriated SSAN to carry out the functions of the Advisory Board.

For the purposes of research, the proposed Subpart A would add a new **Sec. 2023** "Research Protections" defining "legally authorized representative," to mean, unless otherwise provided by law, the individual, or judicial or other body authorized under the applicable law to consent to medical treatment on behalf of another person. It would further require the Secretary to promulgate guidelines to assist researchers working in the areas of elder abuse, neglect, and exploitation, with issues relating to human subjects protections.

To carry out the functions under the proposed Subpart A, a new **Sec. 2024** "Authorization of Appropriations" would authorize to be appropriated $6.5 million for FY2011, and $7.0 million for each of FYs 20012-2014.

Subpart B—Elder Abuse, Neglect, Exploitation Forensic Centers. Subpart B would add a new **Sec. 2031** "Establishment and Support of Elder Abuse, Neglect, and Exploitation Forensic Centers" requiring the Secretary, in consultation with the U.S. Attorney General, to award grants to eligible entities to establish and operate both stationary and mobile forensic centers and to develop forensic expertise pertaining to elder abuse, neglect, and exploitation. Funding would be authorized for the centers to: (1) develop forensic markers that would determine whether abuse or neglect occurred and whether a crime was committed, and determine methodologies for how and when intervention should occur; (2) develop forensic expertise with respect to elder abuse, neglect, and exploitation in order to provide relevant evaluation, intervention, support and advocacy, case review and tracking; and (3) in coordination with the U.S. Attorney General, use data made available by grant recipients under this section to develop the capacity of geriatric health care professionals and law enforcement to collect forensic evidence. Subpart B would authorize to be appropriated $4 million in FY2011, $6 million in FY2012, and $8 million for each of FYs 2013 and 2014 to carry out these activities.

Part II—Programs to Promote Elder Justice

The proposed Title XX, Subtitle B, Part B would establish several grant programs and other activities to promote elder justice. These provisions would be established in the following new Secs. 2041- 2045 and are described below.

Sec. 2041. Enhancement of Long-Term Care. The section would require the Secretary, in coordination with the Secretary of Labor, to carry out activities that provide incentives for individuals to train for, seek, and maintain employment providing direct care in LTC. The Secretary would be required to award grants to eligible entities to conduct programs that offer direct care employees continuing training and varying levels of certification. Grants would also be used to provide for or make arrangements with employers to pay bonuses, or other increased compensation or benefits, to employees who obtain certification. The Secretary would also be required to award grants to eligible entities for training and technical assistance regarding

management practices using methods that are demonstrated to promote retention. The Secretary would be required to develop accountability measures to ensure that funded activities under this subsection benefit direct care workers and increase the stability of the LTC workforce.

The Secretary would also be authorized to make grants to LTC facilities for specified activities that would assist such entities in offsetting costs related to purchasing, leasing, developing, and implementing certified EHR technology designed to improve patient safety and reduce adverse events and health care complications resulting from medication errors. A LTC facility that receives a grant would be required, where available, to participate in state health exchange activities conducted by a state or qualified entity under PHSA Sec. 30143, regarding state grants to promote HIT, to coordinate care and for other purposes the Secretary determines appropriate. The Secretary would be required to develop accountability measures to ensure that these activities help improve patient safety and reduce adverse events and health care complications resulting from medication errors.

The Secretary would be required to adopt electronic standards for the exchange of clinical data by LTC facilities to the Secretary. The standards adopted must be compatible with standards established under current law, as specified, and with general HIT standards. Within 10 years after the date of the proposed law's enactment, the Secretary would be required to have procedures in place to accept the optional electronic submission of clinical data by LTC facilities. The Secretary would be required to promulgate regulations to carry out the adoption of standards for transactions involving clinical data by LTC facilities. Such regulations would require a state, as a condition of the receipt of funds under Part B, to conduct such data collection and reporting as the Secretary determines necessary.

It would authorize to be appropriated $20 million for FY2011, $17.5 million for FY2012, and $15 million for each of FYs 2013 and 2014 to carry out the activities under this section.

Sec. 2042. Adult Protective Service Functions and Grant Program. The section would require the Secretary to ensure that the Department: (1) provides authorized funding to state and local adult protective services (APS) offices that investigate reports of elder abuse, neglect, and exploitation of elders; (2) collects and disseminates data in coordination with DoJ; (3) develops and disseminates information on best practices regarding, and provides training on, carrying out APS; (4) conducts research related to the provision of APS; and (5) provides technical assistance to states and other entities that provide or fund APS. To carry out these functions, the section would authorize to be appropriated $3 million for FY2011, and $4 million for each of FYs 2012-2014.

The section would also require the Secretary to establish two grant programs. The first would award annual grants to enhance APS programs provided by states and local governments. The second would award grants to states for APS demonstration programs. Annual grants awarded to states to enhance APS programs would be distributed to states based on a formula that takes into account the number of individuals aged 60 or older residing in a state relative to the total U.S. population aged 60 or older. States would receive no less than 0.75% of the grant program's annual appropriation. The District of Columbia and U.S. territories would receive no less than 0.1% of the annual appropriation. In order to comply with these minimum amounts, the Secretary would be required to make pro rata reductions in allotments. Grant awards for APS demonstration programs may be used by state and local governments to test: training modules developed for the purpose of detecting or preventing elder abuse; methods to detect or prevent financial exploitation and elder abuse; whether training on elder abuse forensics enhances the detection of abuse by employees of state or local government; and other related matters. For each of FYs 2011-2014, it would authorize to be appropriated $100 million for annual grants to enhance APS programs and $25 million for the APS demonstration grants.

Sec. 2043. Long-Term Care Ombudsman Program Grants and Training. The section would require the Secretary to award grants to eligible entities with relevant expertise and experience in abuse and neglect in LTC facilities or state LTC ombudsman programs to: (1) improve the capacity of state LTC ombudsman programs to respond to and resolve abuse and neglect complaints; (2) conduct pilot programs with state or local LTC ombudsman offices; and (3) provide support for such state LTC ombudsman programs and such pilot programs. The provision would authorize to be appropriated $5 million for FY2011, $7.5 million for FY2012, and $10 million for FYs 2013 and 2014. The provision would also require the Secretary to establish programs to provide and improve ombudsman training with respect to elder abuse, neglect, and exploitation for national organizations and state LTC ombudsman programs. The provision would authorize to be appropriated $10 million for each of FYs 2011-2014.

Sec. 2044. Provision of Information Regarding, and Evaluation of, Elder Justice Programs. To be eligible to receive a grant under Part B, the section would require an applicant to (1) agree to provide the required information to eligible entities conducting an evaluation of the activities funded through the grant; and (2) in the case of an applicant for a certified EHR technology grant, to provide the Secretary with such information as the Secretary may require. It would require the Secretary to reserve a portion of the funds appropriated in each program under Part B (no less than 2%) to be used to provide assistance to eligible entities to conduct validated evaluations of the effectiveness of the activities funded under that program. This provision would not apply to the certified EHR technology grant program, instead the Secretary would be required to conduct an evaluation of the activities funded under this grant program and appropriate grant audits.

Sec. 2045. Report. The section would set forth reporting requirements and add an option for a state's TANF state plan to assist individuals seeking employment in LTC facilities. The HHS Secretary would be required to submit a report to the Elder Justice Coordinating Council and appropriate congressional committees, compiling, summarizing, and analyzing state reports submitted under the APS grant programs and recommendations for legislative or administrative action. The section would also amend the SSA to add an option for a state's TANF state plan to indicate whether the state intends to assist individuals who train for, seek, and maintain employment providing direct care in a LTC facility or in other occupations related to elder care. States that add this option would be required to provide an overview of such assistance.

Protecting Residents of Long-Term Care Facilities

Subsection (b) of Sec. 1913 would establish (1) a National Training Institute for Surveyors and grants to state survey agencies; and (2) requirements for reporting crimes in federally funded LTC facilities.

Specifically, this provision would require the Secretary to enter into a contract to establish and operate the National Training Institute for federal and state surveyors to carry out specified activities that provide and improve the training of surveyors investigating allegations of abuse, neglect, and misappropriation of property in programs and LTC facilities that receive payments under Medicare and/or Medicaid. It would authorize to be appropriated $12 million for each of FYs 2011-2014 to carry out these activities. The HHS Secretary would also be required to award grants to state survey agencies that perform surveys of Medicaid and/or Medicare participating facilities to design and implement complaint investigation systems. It would authorize $5 million for each of FYs 2011-2014 to carry out these activities.

The provision would also amend Part A of Title XI of the SSA by adding the following new **Sec. 1150B** "Reporting to Law Enforcement of Crimes Occurring in Federally Funded Long-Term Care Facilities" requiring the reporting of crimes occurring in federally funded LTC facilities that

receive at least $10,000 during the preceding year. It would require the owner or operator of these facilities to annually notify covered individuals (defined as an owner, operator, employee, manager, agent, or LTC facility contractor) that they are required to report any reasonable suspicion of a crime against a resident or individual receiving care from the facility. Suspected crimes must be reported to the Secretary and one or more law enforcement entities. The timing for reporting suspected crimes would be subject to certain reporting requirements. Failure of a covered individual to report suspicion of a crime would result in a civil money penalty and the Secretary may make a determination to exclude the covered individual form participation in any federal health care program. If an individual is classified as an "excluded individual," any entity that employs them would not be eligible to receive federal funds. The Secretary would be authorized to take into account the financial burden on providers with underserved population in determining any penalty to be imposed. A LTC facility may not retaliate against an employee for making a report. If retaliation occurs, the LTC facility would be subject to a civil money penalty or the Secretary may exclude them from participation in any federal health care program for a period of two years. In addition, each LTC facility must post conspicuously, in an appropriate location, a sign specifying the rights of employees under this section.

National Nurse Aide Registry

Subsection (c) of Sec. 1913 would require the Secretary, in consultation with appropriate government agencies and private sector organizations, to conduct a study on establishing a national nurse aide registry that includes an evaluation. In conducting the study and preparing the report, the Secretary would be required to take into consideration the findings and conclusions of relevant reports and resources. The Secretary would be required to submit a report to the Elder Justice Coordinating Council and appropriate congressional committees containing the findings and recommendations of the study. Based on the recommendations contained in the report, the appropriate congressional committees would be required to take action as determined appropriate. It would authorize to be appropriated SSAN to carry these activities, with funding for the study not to exceed $500,000.

Miscellaneous

Sec. 1921. Protecting Americans and Ensuring Taxpayer Funds in Government Health Care Plans Do Not Support or Fund Physician-Assisted Suicide; Prohibition against Discrimination on Assisted Suicide

This section would prohibit the federal government, and any state or local government or health care provider that receives federal financial assistance under this proposed law (or under an amendment made by this proposed law) or any health plan created under this proposed law (or under an amendment made by this proposed law) from paying for or reimbursing any health care entity for items or services furnished for the purpose of causing, or for the purpose of assisting in causing, the death of any individual, such as by assisted suicide, euthanasia, or mercy killing. It would also prohibit subjecting an individual or institutional health care entity to discrimination on the basis that the entity does not provide any health care item or service furnished for the purpose of causing, or assisting in causing, the death of any individuals, such as by assisted suicide, euthanasia, or mercy killing. The HHS Office of Civil Rights would be designated to receive complaints of discrimination on this basis. Nothing in the above would be construed to apply or to affect any limitation relating to (1) the withholding or withdrawing of medical treatment or medical care; (2) the withholding or withdrawing of nutrition or hydration; (3) abortion; or (4) the

use of an item, good, benefit, or service furnished for the purpose of alleviating pain or discomfort, even if such use may increase the risk of death, so long as it is not also furnished for the purpose of causing, or assisting in causing, death.

Sec. 6008. Imposition of Annual Fee on Branded Prescription Pharmaceuticals Manufacturers and Importers

This section would impose an annual fee on *covered entities*: certain manufacturers and importers of branded prescription drugs (including biological products and excluding orphan drugs). Covered entities would pay annually to the Secretary of the Treasury a total of $2.3 billion, which would be transferred to the Medicare Part B trust fund.

Each covered entity would pay a proportion of the $2.3 billion, calculated by the Secretary, equal to the proportion that specified amounts of each entity's branded prescription drug sales for specified government programs bore to the total such sales of all covered entities for the previous year. The specified amounts of total that would be taken into account are as follows. For sales of not more than $5 million, none would be taken into account. For sales of more than $5 million and not more than $125 million, 10% would be taken into account. For sales of more than $125 million and not more than $225 million, 40% would be take into account. For sales of more than $225 million and not more than $400 million, 75% would be take into account. For sales of more than $400 million, 100% would be take into account.

The Secretary of the Treasury would calculate the proportion to be paid by each covered entity based upon annual reports made by the Secretaries of HHS, Veterans Affairs, and Defense. Reports would contain the total branded prescription drug sales for each covered entity with respect to Medicare Parts B and D, Medicaid, the Department of Veterans Affairs programs, and the Department of Defense programs and TRICARE.

Sec. 6009. Imposition of Annual Fee on Medical Device Manufacturers and Importers

This section would impose an annual fee on *covered entities*: certain manufacturers and importers of medical devices with sales in United States. Sales would exclude those of class II devices typically sold to consumers for less that $100, and those of class I devices.[47]

Covered entities would pay annually to the Secretary of the Treasury a total of $4 billion. Each covered entity would pay proportion of the $4 billion, calculated by the Secretary, that is equal to the proportion that specified amounts of its gross receipts from medical device sales bore to the total gross receipts of all covered entities for the previous year. The specified amounts of total that would be taken into account are as follows. For sales of not more than $5 million, none would be taken into account. For sales of more than $5 million and not more than $25 million, 50% would be taken into account. For sales of more than $25 million, 100% would be take into account.

[47] Under the Federal Food, Drug and Cosmetic Act, medical devices are categorized as class I, class II, or class III according to the amount of controls necessary to ensure their safety and effectiveness. Class I devices (e.g., cotton swabs) require the least controls. Class III devices (e.g., pacemakers) require the most controls. For further information see CRS Report RL32826, *The Medical Device Approval Process and Related Legislative Issues*, by Erin D. Williams.

The Secretary of the Treasury would calculate the proportion to be paid by each covered entity based upon annual reports made by covered entities. Penalties could be imposed for a failure to make required reports.

Appendix. Acronyms Used in the Report

ACIP	Advisory Committee on Immunization Practices
AHRQ	Agency for Healthcare Research and Quality
ARRA	American Recovery and Reinvestment Act
CDC	Centers for Disease Control and Prevention
CHC	Community Health Center
CHIP	Children's Health Insurance Program
CMS	Centers for Medicare and Medicaid Services
EHR	electronic health record
ERISA	Employee Retirement Income Security Act
FCCCER	Federal Coordinating Council for Comparative Effectiveness Research
FQHC	Federally Qualified Health Center
GAO	Government Accountability Office
HELP	Senate Committee on Health, Education, Labor, and Pensions
HHS	Health and Human Services
HIT	Health Information Technology
HIPAA	Health Insurance Portability and Accountability Act
HITECH	Health Information Technology for Economic and Clinical Health Act
HRSA	Health Resources and Services Administration
HPSA	Health Professional Shortage Area
IOM	Institute of Medicine
MA	Medicare Advantage
NF	Nursing Facility
NHSC	National Health Service Corps
NIH	National Institutes of Health
NHDR	National Healthcare Disparities Report
NOHSS	National Oral Health Surveillance System
OMB	Office of Management and Budget
PQRI	Physician Quality Reporting Initiative
QHBP	Qualified Health Benefits Plan
RHQDAPU	Reporting Hospital Quality Data for Annual Payment Update
SG	U.S. Surgeon General
SNF	Skilled Nursing Facility
SSA	Social Security Act
SSAN	such sums as may be necessary
USPSTF	U.S. Preventive Services Task Force

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